Not Reported in N.E.2d
2003-Ohio-3699
(Cite as: 2003 WL 21637968 (Ohio App. 12 Dist.))

CHECK OHIO SUPREME COURT RULES FOR REPORTING OF OPINIONS AND WEIGHT OF LEGAL AUTHORITY.

Court of Appeals of Ohio,
Twelfth District, Butler County.

LaDonna HOWLAND, et al., Plaintiffs-Appellees,
v.
PURDUE PHARMA, L.P., et al.,
Defendants-Appellants.

Nos. CA2002-09-220, CA2002-09-223, CA2002-09-227.

Decided July 14, 2003.

Putative class members sued drugmakers and doctor alleging defective design of drug and breach of express and implied warranties. Plaintiffs moved for class certification. The Court of Common Pleas, Butler County, certified class. Drugmakers appealed. The Court of Appeals, Powell, J., held that: (1) finding that common questions predominated individual issues was not abuse of discretion, and (2) certification of class against doctor was abuse of discretion.

Affirmed in part, reversed in part and remanded.

Valen, P.J., concurred in part, dissented in part, and filed opinion.

[1] Parties ⇐35.71

287k35.71 Most Cited Cases

Putative class members in suit against drugmakers produced evidence that drugmakers engaged in class-wide conduct of failure to warn and defective design of analgesic drug, and thus, finding that common questions of law and fact predominated over issues affecting individual members to satisfy that requirement for certification of class action was not abuse of discretion; there was evidence that drug companies distributed false and misleading promotional material, failed to warn of drug's addiction nature and inappropriate use and sold drug that was defectively designed. Rules Civ.Proc., Rule 23.

[2] Parties ⇐35.71
287k35.71 Most Cited Cases

Questions affecting only individual members of class in suit against physician for prescribing allegedly defectively designed drug predominated over questions of law or fact common to all members of class, and thus, certification of class action against prescribing physician was abuse of discretion, where physician's decision to prescribe drug had to be based on number of factors that were unique to individual patients. Rules Civ.Proc., Rule 23.

[3] Parties ⇐35.71
287k35.71 Most Cited Cases

Putative class members failed to establish that doctor's promotional activities for allegedly defective drug rendered those activities applicable to all class members as common issue that predominated over issues applicable to individual members, and thus, trial court's certification of class as to doctor was abuse of discretion; there was no evidence that doctor's promotional activities impacted more than small percentage of class, and number of times doctor prescribed drug represented only tiny fraction of total prescriptions written for drug. Rules Civ.Proc., Rule 23.
Civil Appeal from Butler County Court of Common Pleas, Case No. CV2001-07- 1651.

Waite, Schneider, Bayless & Chesley Co., LPA, Stanley M. Chesley, Louise M. Roselle, Terrence L. Goodman, Renee A. Infante, Cincinnati, OH; Law Office of Scott J. Frederick, LLC, Scott J. Frederick , Patrick Garretson, Hamilton, OH; Gardner, Ewing & Souza, C. David Ewing, Gary L. Gardner, Damon B. Willis, Louisville, KY; Frankovitch, Anetakis, Colantonio & Simon, Carl Frankovitch, Weirton, WV; David L. Helmers & Associates, David L. Helmers, Shirley Allen Cunningham, Jr., and Gallion, Baker & Bray, William Joseph Gallion, Lexington, KY, for plaintiffs-appellees, LaDonna Howland, Ronald Schaffer, Martha Schaffer, Lillian Lakes, and Fred Lakes.

Vorys, Sater, Seymour and Pease LLP, David S. Cupps, Daniel J. Buckley, Philip J. Smith,

Cincinnati, OH, for defendants-appellants, Purdue Pharma L.P., Purdue Pharma, Inc.

The Purdue Frederick Company, Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., and PRA Holdings, Inc. Lindhorst & Dreidame, Michael F. Lyon, Bradley D. McPeek, Cincinnati, OH, for defendant-appellant, Timothy Smith, D.O.

Ulmer & Berne, LLP, Joseph P. Thomas, Cincinnati, OH; Venable, Baetjer and Howard, LLP, (of counsel) Paul F. Strain, M. King Hill III, Baltimore MD, for defendants-appellants, Abbott Laboratories, and Abbott Laboratories, Inc.

Blank Rome Comisky & McCauley LLP, Nathaniel R. Jones, Sharon J. Zealey, Cincinnati, OH, for amicus curiae, National Medical Association.

Daniel N. Abrahamson, Judith K. Appel, Drug Policy Alliance, Oakland, CA; John Giglio, American Pain Foundation, Baltimore, OH, Mary Baluss, Counsel, National Foundation for the Treatment of Pain, Washington DC; and James P. Langendorf, Middletown, OH, for amici curiae, American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in support of defendants-appellants.

Bricker & Eckler LLP, Quintin F. Lindsmith, Columbus, OH; Covington & Burling, (of counsel) David H. Remes, Jason P. Gluck, Washington DC, for amicus curiae, Pharmaceutical Research and Manufacturers of America.

POWELL, J.

***1** {¶ 1} Defendants-appellants Purdue Pharma L.P., et al., appeal a decision from the Butler County Common Pleas Court certifying a class action brought by plaintiffs-appellees, LaDonna Howland, et al., regarding the prescription drug, OxyContin®.

{¶ 2} OxyContin is an analgesic drug, which is made in tablet form and bound by a time-released matrix. The controlled release nature of OxyContin permits continuous dosing for a 12-hour period from a single tablet. Some persons have abused OxyContin by crushing or dissolving the tablet thereby permitting the immediate administration of the tablet's entire 12-hour dose. The existing formulation does not contain an "antagonist" that would prevent its abuse from crushing or dissolving a tablet.

{¶ 3} OxyContin was designed, tested, manufactured, promoted, marketed, sold, and distributed by Purdue Pharma, L.P., along with its affiliates, Purdue Pharma, Inc., The Purdue Frederick Company, Purdue Pharmaceuticals, L.P., The P.F. Laboratories, Inc., and PRA Holdings, Inc. (hereinafter, "Purdue"). Purdue had an agreement with Abbott Laboratories and Abbott Laboratories, Inc. (hereinafter, "Abbott") to "co-promote" OxyContin to hospitals and certain physicians.

{¶ 4} Dr. Timothy Smith is a licensed physician in this state, who specializes in the treatment of pain. Dr. Smith has prescribed OxyContin for some of his patients, including LaDonna Howland. Howland was first prescribed OxyContin for pain stemming from injuries she sustained in an automobile accident in 1999. She continued receiving prescriptions for OxyContin for approximately 18 months. Howland has allegedly experienced addiction, drug dependency and withdrawal symptoms as a result of her use of OxyContin.

{¶ 5} Ronald Schaffer was first prescribed OxyContin (by a physician other than Dr. Smith) after undergoing heart surgery in 1998. He continued receiving prescriptions for OxyContin for approximately two years. Lillian Lakes was first prescribed OxyContin (by a physician other than Dr. Smith) following a mastectomy in November 1999. She continued receiving prescriptions for the drug through 2000. Both Schaffer and Lakes allegedly suffered several adverse effects, including drug dependence, as a result of their using OxyContin.

{¶ 6} On December 31, 2001, LaDonna Howland, along with Ronald Schaffer and his wife, Martha, and Lillian Lakes and her husband, Fred, (hereinafter, referred to collectively as "appellees") filed a second amended class action complaint for damages on behalf of themselves and all others similarly situated in this state who were improperly prescribed OxyContin and damaged by the use or abuse of that drug. Named as defendants in the

action were Purdue, Abbott and Dr. Smith (hereinafter, referred to collectively as "appellants").

{¶ 7} Appellees alleged that appellants failed to exercise reasonable care in the design, manufacture, marketing, promotion, sale, prescribing or distribution of OxyContin; failed to warn them and others similarly situated of the risks posed by OxyContin; breached their expressed warranty that OxyContin was a safe, effective treatment for pain; and breached their implied warranty that OxyContin was of merchantable quality and safe for its intended use. Appellees sought certification for the following three classes:

***2** {¶ 8} "(a) All persons in the State of Ohio that were prescribed OxyContin and thereafter suffered, and/or continue to suffer, the effects of the drug such as the risk of addiction, actual addiction, and the consequences of addiction;

{¶ 9} "(b) All persons in the state of Ohio that were prescribed OxyContin and thereafter suffered, and/or continue to suffer, the effects of the drug such as physical, mental, and/or emotional harm, death and/or loss of consortium, as a result of the use of OxyContin;

{¶ 10} "(c) All persons in the State of Ohio that suffered, and/or continue to suffer, the effects of the drug such as physical, mental, and/or emotional harm, death and/or loss of consortium, as a result of the use and abuse of OxyContin by others."

{¶ 11} In February 2002, the trial court heard oral arguments on the class certification issue. All parties submitted documentary evidence, including depositions, in support of their respective positions. On August 30, 2002, the trial court granted appellees' motion to certify the three proposed classes.

{¶ 12} Purdue, Abbott and Dr. Smith all separately appealed from the trial court's decision. The appeals have been consolidated for review.

{¶ 13} Purdue's assignment of error states:

{¶ 14} "THE TRIAL COURT ERRED IN GRANTING PLAINTIFFS/APPELLEES' MOTION FOR CLASS CERTIFICATION."

{¶ 15} Abbott's assignment of error states:

{¶ 16} "THE TRIAL COURT ERRED IN GRANTING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION AS TO DEFENDANTS-APPELLANTS ABBOTT LABORATORIES, INC."

{¶ 17} Dr. Smith's assignment of error states:

{¶ 18} "THE TRIAL COURT ABUSED ITS DISCRETION BY CERTIFYING A CLASS ACTION AGAINST THE DEFENDANT TIMOTHY SMITH, M.D. [sic]."

{¶ 19} Given the similarities of the issues presented, these assignments of error will be addressed jointly.

{¶ 20} Appellants each argue that the trial court erred in granting appellees' motion to certify the three proposed classes against them because appellees failed to meet the requirements of Civ.R. 23(A) and (B). [FN1]

FN1. {¶ a} Civ.R. 23(A) and (B) state:
{¶ b} "Rule 23. CLASS ACTIONS
{¶ c} "(A) Prerequisites to a class action. One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.
{¶ d} "(B) Class actions maintainable. An action may be maintained as a class action if the prerequisites of subdivision (A) are satisfied, and in addition:
{¶ e} "(1) the prosecution of separate actions by or against individual members of the class would create a risk of
{¶ f} "(a) inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the party opposing the class; or

> {¶ g} "(b) adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; or
> {¶ h} "(2) the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole; or
> {¶ i} "(3) the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (a) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (b) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (c) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (d) the difficulties likely to be encountered in the management of a class action."

{¶ 21} "The following seven requirements must be satisfied before an action may be maintained as a class action under Civ.R. 23:(1) an identifiable class must exist and the definition of the class must be unambiguous; (2) the named representatives must be members of the class; (3) the class must be so numerous that joinder of all members is impracticable; (4) there must be questions of law or fact common to the class; (5) the claims or defenses of the representative parties must be typical of the claims or defenses of the class; (6) the representative parties must fairly and adequately protect the interests of the class; and (7) one of the three Civ.R. 23(B) requirements must be met." *Hamilton v. Ohio Sav. Bank,* 82 Ohio St.3d 67, 71, *1998-Ohio-365,* citing Civ.R. 23(A) and (B), and *Warner v. Waste Mgt., Inc.* (1988), 36 Ohio St.3d 91, 521 N.E.2d 1091. The first two of these seven prerequisites are implicitly required by Civ.R. 23, while the remaining five are explicitly set forth therein. *Id.* at 94, 521 N.E.2d 1091. The trial court must find, by a preponderance of the evidence, that all seven of these requirements have been met before certifying the case as a class action. *Id.*

***3** {¶ 22} "A trial judge has broad discretion in determining whether a class action may be maintained and that determination will not be disturbed absent a showing of an abuse of discretion." *Marks v. C.P. Chem. Co. Inc.* (1987), 31 Ohio St.3d 200, 509 N.E.2d 1249, syllabus. "However, the trial court's discretion in deciding whether to certify a class action is not unlimited, and indeed is bounded by and must be exercised within the framework of Civ.R. 23. The trial court is required to carefully apply the class action requirements and conduct a rigorous analysis into whether the prerequisites of Civ.R. 23 have been satisfied." *Hamilton,* 82 Ohio St.3d at 70, 694 N.E.2d 442.

{¶ 23} We conclude that the trial court did not abuse its discretion in determining that the case could proceed as a class action against Purdue and Abbott. We also conclude, however, that the class definitions need to be modified so that they do what appellees themselves claim, i.e., "eliminate [ ] Ohio residents who initially secured OxyContin® through unlawful means."

{¶ 24} First, the definitions of the three classes proposed by appellees are precise enough to permit the trial court to determine, within a reasonable effort, whether a particular individual is a class member. See *Hamilton* at 72, 694 N.E.2d 442. Purdue and Abbott argue that the proposed class definitions include those who obtained OxyContin prescriptions illegally. To this extent we agree that the class definitions need to be modified to ensure that they eliminate any Ohio resident who initially secured OxyContin through unlawful means. Appellees argue that such modification is not necessary, but acknowledge that "[t]o the extent * * * the class definition needs modification * * * this Court can affirm the Trial Court's certification and require a modification of the class definition." We choose to do just that. See *Warner,* 36 Ohio St.3d at 99, 521 N.E.2d 1091. On remand, the trial court will modify the class definitions to ensure that they

eliminate any Ohio resident who initially secured OxyContin through unlawful means.

{¶ 25} Purdue and Abbott also argue that appellees have not defined the term, "suffered," as used in the definitions of the classes. However, the trial court has properly ruled that it will give the term its common and ordinary meaning. Subject to the trial court's modification of the class definitions to ensure that Ohio residents who initially secure OxyContin through unlawful means are eliminated from the three classes, the class definitions proposed by appellees are unambiguous and class members are readily identifiable.

{¶ 26} Second, it appears from the evidence presented that the named representatives are members of at least one of the three proposed classes and that all of the named representatives have proper standing to sue. "The class membership prerequisite requires only that 'the representative have proper standing. In order to have standing to sue as a class representative, the plaintiff must possess the same interest and suffer the same injury shared by all members of the class that he or she seeks to represent .' " *Hamilton,* 82 Ohio St.3d at 74, 694 N.E.2d 442, quoting 5 Moore's Federal Practice (3 Ed.1997) 23-57, Section 23.21[1]. Here, each of the appellees possesses the same interest and suffered the same injury shared by the members of the class they will represent.

*4 {¶ 27} Third, there is evidence to show that each of the proposed classes is so numerous that joinder of all members is impracticable. Over one million prescriptions for OxyContin have been filled in retail pharmacies in this state from June 1998 to December 2001. This evidence is sufficient to establish the impracticality of joinder against Purdue and Abbott. See *Marks,* 31 Ohio St.3d at 202, 509 N.E.2d 1249, *Warner,* 36 Ohio St.3d at 97, 521 N.E.2d 1091, and *Hamilton,* 82 Ohio St.3d at 75, 694 N.E.2d 442.

{¶ 28} Fourth, there is evidence to show the existence of questions of fact and law that are common to all members of the proposed classes. "It is not necessary that all the questions of law or fact raised in the dispute be common to all the parties. If there is a common nucleus of operative facts, or a common liability issue, the rule is satisfied." *Id.* at 77, 694 N.E.2d 442, citing *Marks,* 31 Ohio St.3d at 202, 509 N.E.2d 1249. Here, there are common issues of fact regarding whether Purdue and Abbott negligently promoted or marketed OxyContin, and whether Purdue and Abbott knowingly concealed material facts about the nature and qualities of OxyContin from appellees and the classes of persons they represent.

{¶ 29} Fifth, appellees' claims are typical of those of the classes they represent, and there is no express conflict between the class representatives and the classes. See *Hamilton,* 82 Ohio St.3d at 77, 694 N.E.2d 442. Purdue argues that typicality cannot be established where numerous questions of law and fact exist. We disagree. While the defenses or claims of the class representatives must be typical of the defenses or claims of the class members, they need not be identical. *Planned Parenthood Assn. of Cincinnati, Inc. v. Project Jericho* (1990), 52 Ohio St.3d 56, 64, 556 N.E.2d 157. Here, appellees' causes of action will be identical to the ones raised by the class members they represent, and although there may be some defenses that will not apply to all class members, many of the defenses will be the same.

{¶ 30} Sixth, there is evidence to show that the class representatives are adequate to represent members of the proposed classes. The "adequacy of representation" requirement "is generally divided into a consideration of the adequacy of the representative and the adequacy of counsel." *Marks,* 31 Ohio St.3d at 203, 509 N.E.2d 1249. "A representative is deemed adequate so long as his interest is not antagonistic to that of other class members." *Id* . Here, appellees' claims are not antagonistic to those of the class members they represent, since they are all based on Purdue's and Abbott's alleged wrongful conduct in designing, manufacturing or promoting OxyContin. Furthermore, appellees' attorneys are experienced in handling class action litigation.

{¶ 31} Seventh, the requirements for certifying a class action under Civ.R. 23(B)(3) have been met in this case as to Purdue and Abbott. Civ.R. 23 provides in relevant part:

{¶ 32} "**(B) Class actions maintainable.** An action may be maintained as a class action if the prerequisites of subdivision (A) are satisfied, and in addition:

*5 {¶ 33} " * * *

{¶ 34} "(3) the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (a) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (b) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (c) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (d) the difficulties likely to be encountered in the management of a class action."

{¶ 35} Both Purdue and Abbott argue that the trial court abused its discretion in finding that questions of law and fact common to members of the classes predominate over issues affecting only individual members of the classes. Purdue and Abbott also argue that a class action is not the superior method of resolving this controversy because individual issues predominate over common ones.

{¶ 36} However, it has been held that "a claim will meet the predominance requirement when there exists generalized evidence which proves or disproves an element on a simultaneous, class-wide basis, since such proof obviates the need to examine each class member's individual position." *Cope v. Metro. Life Ins. Co.*, 82 Ohio St.3d 426, 429-430, *1998-Ohio-405,* quoting *Lockwood Motors, Inc. v. Gen. Motors Corp.* (D.Minn.1995), 162 F.R.D. 569, 580. "The key should be whether the efficiency and economy of common adjudication outweigh the difficulties and complexity of individual treatment of class members' claims." Miller, An Overview of Federal Class Actions: Past, Present and Future (2 Ed.1977), at 45, quoted in *Warner,* 36 Ohio St.3d at 96, 521 N.E.2d 1091.

[1] {¶ 37} Here, appellees presented evidence that Purdue and Abbott engaged in a common, class-wide course of conduct, inasmuch as they failed to issue warnings regarding such matters as OxyContin's addictive nature, the inappropriateness of using OxyContin for certain ailments like arthritis pain, and the danger of crushing OxyContin tablets. There was also evidence presented showing that Purdue and Abbott distributed false and misleading promotional materials, and promoted and sold a defectively designed product (i.e., OxyContin, which lacked an antagonist). As the trial judge explained, certifying appellees' claims as a class action will allow the trial court to resolve the common questions raised by Purdue's and Abbott's conduct before addressing the individual questions of each class member. If the trial court finds that Purdue and Abbott were not negligent, did not fail to provide warning, or did not breach any express or implied warranties, the case, or at least that cause of action, will end as to Purdue and Abbott if they can make such a showing. However, forcing appellees and the class members they represent to pursue Purdue and Abbott individually would result in the presentation of redundant evidence and arguments, and increased litigation costs.

*6 {¶ 38} Abbott also argues that the trial court erred in finding that it was a "manufacturer, distributor and seller" of OxyContin. Abbott argues that it only co-promoted OxyContin to a limited group of physicians. Abbott argues that only one of the four claims appellees have brought against it, namely, the negligence claim, can be asserted against it, because the remaining claims (for strict liability/failure to warn, and breach of express and implied warranties) are not available against a nonmanufacturer or nonseller as a matter of law. However, we agree with appellees that these issues, which will involve an analysis of the merits of the case, should be addressed by way of a motion to dismiss or a motion for summary judgment, rather than this interlocutory proceeding.

{¶ 39} We acknowledge that it "is conceivable that a significant amount of time may be spent in this case litigating questions affecting only individual members of the classes. However, clockwatching is neither helpful nor desirable in determining the propriety of class certification. * * * A court should not 'determine predominance by comparing the time that the common issues can be anticipated to consume in the litigation to the time that individual issues will require. Otherwise, only the most complex common questions could predominate since such issues tend to require more time to litigate than less complex issues.' " (Citations omitted.) *Hamilton,* 82 Ohio St.3d at 85,

694 N.E.2d 442. Accordingly, we conclude that the trial court did not abuse its discretion in determining that the common questions predominate over the individual questions in the action brought against Purdue and Abbott, and that a class action is the superior method of resolving this controversy.

[2] {¶ 40} While we find that the trial court did not abuse its discretion by certifying the class action against Purdue and Abbott, we nevertheless conclude that the trial court *did* abuse its discretion by certifying a class action against Dr. Smith because, as to him, questions affecting only individual members of the class predominate over the questions of law or fact common to members of the classes. Alternatively, we conclude that a class action is not the superior method for the fair and efficient adjudication of the controversy.

{¶ 41} Appellees have proceeded against Dr. Smith on two bases. First, they have argued that he was negligent in prescribing OxyContin to his patients, including class representative LaDonna Howland.

{¶ 42} However, a physician's decision to prescribe OxyContin to any patient must be based on a number of factors that are unique to that individual. As Dr. Smith states:

{¶ 43} "The claims of each putative class member arise out of unique circumstances, including different levels of exposure to OxyContin, different alleged effects of the exposure, and different reasons for the exposure. These unique circumstances, which are part and parcel of the prescribing decision * * *, undermine any conclusion that elements common to all claimants predominate over the individual issues."

*7 {¶ 44} Therefore, we conclude that as to this aspect of appellees' claims, the questions of fact affecting only individual members predominate over questions of law and fact common to the members of the classes.

[3] {¶ 45} Second, appellees have sought to emphasize Dr. Smith's role in "promoting" OxyContin through his involvement in educational presentations, in which Dr. Smith touted the benefits of OxyContin. Appellees cite Dr. Smith's "promotional" activities as their justification for naming Dr. Smith as one of the defendants in this class action. However, in our view, Dr. Smith's promotional activities provide an insufficient basis for concluding that common issues of fact and law predominate over issues affecting only individual members of the class.

{¶ 46} The facts in this case show that Dr. Smith's activities could have impacted only a small percentage of the certified classes. For example, it is unknown how many physicians who prescribed OxyContin did so because of Dr. Smith's presentations. Furthermore, while there was evidence to show that Dr. Smith prescribed OxyContin more than 300 times in less than a three-month period, this represents only a tiny fraction of the more than one million prescriptions for OxyContin that were written in this state from June 1998 to December 2001. And it should be remembered that Dr. Smith is not being sued as a representative of a class of defendant physicians in this state who have prescribed OxyContin. Appellees have failed to establish a connection between the injuries of any plaintiff or class member other than Howland to Dr. Smith's actions. Under these circumstances, we believe that it was unreasonable for the trial court to find that questions of law or fact common to members of the classes predominated over any questions affecting only their individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. For these reasons, we conclude that the trial court abused its discretion in certifying the class action against Dr. Smith.

{¶ 47} Purdue Pharma's and Abbott's assignments of error are sustained in part and overruled in part. Dr. Smith's assignment of error is sustained.

{¶ 48} The trial court's judgment is affirmed in part and reversed in part, and this cause is remanded to the trial court for further proceedings consistent with this opinion.

BROGAN, J. [FN*], concurs.

FN* Brogan, J., of the Second Appellate District, sitting by assignment of the Chief

Justice, pursuant to Section 5(A)(3), Article IV of the Ohio Constitution.

VALEN, P.J., concurs in part and dissents in part.

VALEN, P.J., concurring in part and dissenting in part.

{¶ 49} I concur with the majority's opinion affirming the trial court's decision granting appellees' motion for class certification as to Purdue and Abbott, but I respectfully dissent from the majority's opinion overruling the trial court's class certification against Dr. Smith, for the following reasons.

{¶ 50} I believe that the trial court's decision to certify appellees' class action against Dr. Smith should be affirmed. Smith's connection with OxyContin went beyond prescribing the drug to many of his patients. Like Abbott, Smith promoted OxyContin to physicians in this state, albeit, on a smaller scale. Therefore the same questions of law and fact that will be common to members of the classes with respect to Purdue and Abbott will, likewise, exist with respect to Smith. The majority has failed to provide a sufficient reason for finding that the Civ.R. 23(B)(3) "predominance" and "superiority" standards have been met with respect to Abbott but not Dr. Smith. Therefore, I respectfully dissent.

2003 WL 21637968 (Ohio App. 12 Dist.), 2003-Ohio-3699

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Only the Westlaw citation is currently available.

United States District Court,
D. Minnesota.

In re: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

No. MDL 01-1396 JRTFLN.

March 27, 2003.

J. Gordon Rudd, Jr. and Charles S. Zimmerman, Zimmerman Reed, P.L . L.P., Minneapolis, MN; Steven E. Angstreich, Michael Coren, and Carolyn Lindheim, Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C., Woodcrest Pavilion, Cherry Hill, NJ; James T. Capretz, Capretz & Assoc., Newport Beach, CA; and Joe D. Jacobson, Green, Schaaf & Jacobson, P.C., St. Louis, MO, for plaintiffs.

Tracy J. Van Steenburgh, Halleland, Lewis, Nilan, Sipkins & Johnson, Minneapolis, MN; James C. Martin and David E. Stanley, Reed Smith Crosby Heafey LLP, Los Angeles, CA; Steven M. Kohn, Reed Smith Crosby Heafey LLP, Oakland, CA, for defendant.

MEMORANDUM OPINION AND ORDER ON MOTION FOR CLASS CERTIFICATION

TUNHEIM, J.

***1** On April 18, 2001, the cases comprising this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings under 28 U.S.C. § 1407. This matter is now before the Court on plaintiffs' motion for class certification pursuant to Rule 23 of the Federal Rules of Civil Procedure. For the reasons discussed below, plaintiffs' motion is granted in part and denied in part.

BACKGROUND

I. Factual Background [FN1]

FN1. The facts recited in this section are based upon the submissions of the parties and should not be construed as findings of the Court.

Defendant St. Jude Medical, Inc. ("St.Jude"), a company with headquarters and manufacturing facilities in Minnesota, manufactures a variety of medical devices including prosthetic heart valves. Such valves are surgically implanted into patients whose natural valves have been damaged by disease. Among St. Jude's products is the "Silzone" heart valve, which has a coating of silver on the sewing cuff, the part of the valve that is sewn to the patient's body. Aside from the silver coating, the Silzone valve is essentially the same as other St. Jude heart valves that have been approved by the U .S. Food and Drug Administration ("FDA") since 1995. Because silver has been known to have anti-microbial properties, St. Jude introduced the silver-coated valves to combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a well-known possible consequence of prosthetic heart valve implantation.

The FDA approved the Silzone valve for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis, as no clinical tests had been performed to study this claim. [FN2] After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multinational clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. Approximately 36,000 Silzone valves have been implanted in patients worldwide, with approximately 10,535 of these in the United States. AVERT was originally intended to involve 4,400 heart valve patients. However, the study enrolled only 792 patients, with approximately half of those receiving Silzone-coated valves and another half, the control group, receiving conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

FN2. The FDA also required that all labels bearing the name "Silzone" must carry the following statement: "No clinical studies

have been performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis." (Pl.Ex. 10.)

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more likely to experience a complication called paravalvular leak, [FN3] requiring the prosthetic valve to be removed and replaced with another valve, compared to recipients of conventional valves. The data showed that 2 percent of AVERT participants with Silzone valves required such an "explant," while only .25 percent of participants with conventional valves required the procedure. On January 21, 2000, the monitoring board decided to suspend enrollment in the AVERT trial because of this increase in paravalvular leak. [FN4] On the same day, St. Jude voluntarily recalled all unimplanted Silzone products. As part of the recall, St. Jude immediately notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak.

FN3. Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient's tissue.

FN4. Although enrollment in AVERT was suspended, the participants continue to be monitored, and data are still collected and studied.

II. Procedural History and Class Structure

***2** The MDL plaintiffs filed a Consolidated Amended Class Action Complaint in this Court on October 22, 2001. The complaint alleges five causes of action, including counts of strict liability, breach of implied and express warranties, negligence, medical monitoring, and violation of Minnesota's consumer fraud and deceptive trade practices statutes.

Plaintiffs seek certification of two classes. Class I (the "monitoring class") is comprised of every patient in the United States who still has a Silzone valve implanted. Because explantation surgery is not advised for all patients, many Silzone valve recipients still have the Silzone valve. Class I seeks equitable relief in the form of a medical monitoring program that would watch for side effects associated with defective heart valves. This would include an epidemiological program to collect data and study the effects of the Silzone valves. This monitoring program would be paid for by a trust account funded by St. Jude.

Class II (the "injury class") consists of all people in the United States who received a Silzone valve and who have sustained physical injuries due to the valve, including but not limited to injuries requiring explantation surgery and injuries resulting in death. Class II seeks money damages. [FN5]

FN5. It is possible that a person will be a member of both classes. For example, some plaintiffs may have suffered injuries due to the Silzone valve but still have the valve implanted.

ANALYSIS

To qualify for class treatment, an action must first satisfy the threshold requirements of Federal Rule of Civil Procedure 23(a), and must then satisfy one of the three subsections of Rule 23(b). Plaintiffs seek certification of all claims by both classes pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure. Plaintiffs also seek certification of Class I pursuant to Rules 23(b)(1)(A) and 23(b)(2). District courts have broad discretion to decide whether or not to certify a class under Rule 23. *Lockwood Motors, Inc. v. General Motors Corp.*, 162 F.R.D. 569, 573 (D.Minn.1995).

Part I of this Order analyzes the threshold requirements of Rule 23(a). Part II analyzes whether the proposed classes merit certification under any of the three provisions of Rule 23(b) that are at issue in this case.

I. Requirements of Rule 23(a)

A. Numerosity

St. Jude does not dispute that both proposed classes meet the numerosity requirements of Rule 23(a)(1). Class I consists of approximately 10,535 individuals, and plaintiffs estimate that Class II consists of more than 1,000 individuals. The Court determines that joinder of all members of either proposed class would be impracticable, and therefore concludes that plaintiffs satisfy the numerosity requirement.

B. Commonality

Rule 23(a)(2) requires that there be "questions of law or fact common to the class." This requirement is satisfied when the legal question linking the class members is substantially related to the resolution of the litigation even though the individuals may not be identically situated. *DeBoer v. Mellon Mortgage Co.,* 64 F.3d 1171, 1174 (8th Cir.1995). Commonality may be satisfied where one issue pervades all the class members' claims. *Paxton v. Union Nat'l Bank,* 688 F.2d 552, 561 (8th Cir.1982) . St. Jude contends that any claim of commonality in this case is "blurred by a host of individual queries." (Def. Br. at 35.) Plaintiffs respond that there is at least one significant question that links all the class members' claims--whether a defect caused by adding the Silzone coating to the St. Jude heart valves caused or risks certain injuries. While St. Jude is correct that there may be individual variations in the factual circumstances of some class members, that is not enough to defeat commonality. The Court finds that the question of the Silzone valve's alleged defect is common to all members of both classes, and that Rule 23(a)(2) is therefore satisfied.

C. Typicality

***3** The Rule 23(a)(3) typicality requirement requires a "demonstration that there are other members of the class who have the same or similar grievances as the plaintiff." *Donaldson v. Pillsbury Co.,* 554 F.2d 825, 830 (8th Cir.1977); *In re Lutheran Brotherhood Variable Ins. Prod. Co. Sales Practices Lit.,* 201 F.R.D. 456, 459 (D.Minn.2001). The burden is "fairly easily met so long as other class members have claims similar to the named plaintiff." *DeBoer,* 64 F.3d at 1174. Moreover, "[f]actual variations in the individual claims will not normally preclude class certification if the claim arises from the same event or course of conduct as the class claims, and gives rise to the same legal or remedial theory." *Alpern v. UtiliCorp United, Inc.,* 84 F.3d 1525, 1540 (8th Cir.1996).

The named plaintiffs contend that their claims are typical because each representative has at least one Silzone valve implanted, and therefore makes the same allegations regarding risk of injury stemming from the valve. Likewise, named Class II plaintiffs allege that they have all sustained some injury due to the Silzone valves that were formerly implanted in them. St. Jude argues that because each plaintiff's case has different factual circumstances, such as varying types of care, treatment, and magnitude of alleged injuries, no plaintiff is typical of all class members.

St. Jude is certainly correct that none of the plaintiffs' cases are factually identical. These arguments, however, are more relevant to the Court's Rule 23(b)(3) analysis. *See Lutheran Brotherhood,* 201 F.R.D. at 459-60 (noting that factual variations are less relevant to typicality analysis than to questions of predominance and superiority). Even if the named plaintiffs' cases do exhibit different factual circumstances, each of them clearly arises "from the same event or practice or course of conduct that gives rise to the claims of the other class members and [is] based on the same legal theor[ies]." *Hurd v. Monsanto Co.,* 164 F.R.D. 234, 239 (S .D. Ind.1995). Specifically, all of the plaintiffs' contentions arise from St. Jude's design, manufacture, marketing, and sales of the Silzone valve. These contentions address the ultimate question in the lawsuit, and the Court finds that they satisfy the typicality requirement.

D. Adequacy of Representation

The final requirement of Rule 23(a) is that "the representative parties will fairly and adequately protect the interests of the class." Fed.R.Civ.P. 23(a)(4). This rule has two requirements. First, the representatives' attorneys must be able and willing to prosecute the action competently and vigorously. Second, each representative's interest must be "sufficiently similar to those of the class that it is unlikely that their goals and viewpoints will diverge." *Parkhill v. Minnesota Mutual Life Ins. Co.,* 188 F.R.D. 332, 339 (D.Minn.1999).

St. Jude does not challenge the adequacy of plaintiffs' counsel. It does, however, contend that a conflict of interest could arise between plaintiffs,

and that this potential conflict makes the representative plaintiffs inadequate. St. Jude points to *Thompson v. American Tobacco Co., Inc.,* 189 F.R.D. 544 (D.Minn.1999), in support. In that case, the court found the representatives of a proposed class of cigarette smokers to be inadequate because a conflict of interest could arise between plaintiffs. *Id.* at 551. *Thompson,* however, is inapposite because the class in that case was structured far differently than the proposed classes here. The proposed class in *Thompson* encompassed people who had smoked a cigarette manufactured by the defendant and wished to participate in a smoking cessation and/or medical monitoring program. *Id.* at 548. Thus, the proposed class included people who had smoked only one cigarette up to current smokers who suffered from smoking- related illnesses. *Id.* However, even though the proposed class encompassed people with smoking-related illnesses, the plaintiffs sought to expressly reserve from the class any claims for personal injury. *Id.* The Court found that this effort to tailor the class to achieve certification could jeopardize class members' future claims for personal injuries, if a subsequent court found that any class action decision was *res judicata. Id.* at 550-551.

***4** In this case, the proposed classes are not nearly so wide-ranging as the single omnibus class in *Thompson.* Here, plaintiffs have divided the classes between those who have suffered some injury traceable to a Silzone valve and those for whom injury is a mere possibility. The class makes no explicit reservation of the kind used in *Thompson.* Plaintiffs contend that there is no conflict of interest between them because they all seek to "prov[e] St. Jude's wrongful conduct and establish[ ] St. Jude's liability" for monitoring for Class I and damages for Class II. (Pl. Br. at 35.) The Court agrees, and finds that plaintiffs all have the same incentive to pursue claims against St. Jude. The Court finds no conflict of interest that would render plaintiffs inadequate representatives of their classes. Therefore, the adequacy component of Rule 23 is satisfied.

The Court finds that plaintiffs have satisfied all the threshold requirements of Rule 23(a). The Court must now determine whether plaintiffs have satisfied any component of Rule 23(b).

II. Requirements of Rule 23(b)

Plaintiffs seek certification under three provisions of Rule 23(b). They first seek to certify both classes under Rule 23(b)(3), which permits certification where plaintiffs can show that common questions predominate and that a class action is the superior method to adjudicate the controversy. Plaintiffs also seek to certify Class I, the monitoring class, under Rule 23(b)(2), which permits injunctive relief if plaintiffs can show that St. Jude acted or refused to act on grounds generally applicable to the class. Finally, plaintiffs seek certification of Class I under Rule 23(b)(1)(A), which provides for class certification when separate actions would create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for the party opposing the class. [FN6]

> FN6. The master complaint in this case also alleges that class certification is appropriate under Rule 23(b)(1)(B). However, plaintiffs have stated that they are not moving for certification under Rule 23(b)(1)(B), so the Court will not analyze that rule.

A. Common Law Claims

1. Rule 23(b)(3)--Both Classes

Plaintiffs seek certification of both classes pursuant to Rule 23(b)(3). This rule has two primary requirements: (1) that common questions of law or fact predominate over any questions affecting only individual class members; and (2) that a class action is superior to other available methods of adjudicating the controversy. Fed.R.Civ.P. 23(b)(3). St. Jude argues that certification under Rule 23(b)(3) is not appropriate because there are too many factual and legal differences among the class members, thus destroying predominance. St. Jude also contends that a class action would not be a superior method of adjudicating either class's allegations because of the inherent difficulties in dealing with the laws of many states.

a. Predominance

The Court has already determined that common questions of law and fact exist in this case. Now it must determine whether these common issues predominate over those unique to individual class members. "There are no bright line rules to

determine whether common questions predominate." *In re Select Comfort Corp. Securities Lit .*, 202 F.R.D. 598, 610 (D.Minn.2001). Rather, "the fundamental question is whether the group aspiring to class status is seeking to remedy a common legal grievance." *Lockwood Motors,* 162 F.R.D. at 580 (quoting 3B *Moore's Federal Practice* ¶ 23.45 (2d ed.1995)).

***5** St. Jude argues that no set of facts is so "generic" that it would be relevant to prove issues of liability, causation, and damages for either Class I or Class II. This argument is similar to that made by the defendant in another medical device class action, *Haley v. Medtronic, Inc.,* 169 F.R.D. 643 (C.D.Cal.1996). Like the defendant in that case, St. Jude focuses on the fact that individual questions for each plaintiff will be critical because each patient has unique medical circumstances causing him or her to react differently to the Silzone valve. *See id.* at 650. Like the court in *Haley,* this Court rejects St. Jude's argument because it "ignores the fact that plaintiffs' claims actually focus on [St. Jude's] liability and [St. Jude's] conduct with regard to the [Silzone valves]--not on their effect on the plaintiffs." *Id.* Plaintiffs' allegations do not relate to any course of conduct between St. Jude and the plaintiffs; they relate only to St. Jude's liability for its course of conduct in designing, manufacturing, marketing, and selling the Silzone valves. The predominance inquiry therefore focuses on questions relating to that conduct. *Cf. Hum v.. Dericks,* 162 F.R.D. 628, 639-40 (D. Hawaii 1995) (holding that individual patient issues predominate where crux of plaintiffs' complaint did not involve manufacturer's liability or defective nature of device, but on physicians' implantation of the device). "When determining whether common questions predominate, courts focus on the liability issue ... and if the liability issue is common to the class, common questions are held to predominate over individual questions." *Select Comfort Corp.,* 202 F.R.D. at 610 (citation and internal quotation marks omitted). *See also In re Telectronics Pacing Systems, Inc.,* 172 F.R.D. 271, 288 (S.D.Ohio 1997) ("Numerous courts have found that common issues predominate when a large number of lawsuits arise from a single disaster or single course of conduct.") Because St. Jude's course of conduct was uniform across all plaintiffs of both classes, the Court agrees with plaintiffs that common questions of fact and law predominate for each class.

St. Jude argues that plaintiffs do not satisfy the predominance requirement, noting that medical product liability actions are rarely certified as class actions. Although this is generally true, the cases that St. Jude cites are markedly different from the present case, as will be shown below. Instead, the Court finds this case to be more similar to the *Telectronics* litigation, in which a 23(b)(3) class was certified despite "the general rule that medical products liability actions require extensive proof of individualized issues." *Id.* In *Telectronics,* the court found that the "general rule" did not apply because the action involved only two products, one manufacturer, one alleged defect, and did not raise overarching questions of causation. *Id.* at 288-89. The Court finds that this case, like *Telectronics,* "does not involve many of the factual and legal complications [that] prevented certification in other medical products liability actions." *Id.* at 288.

***6** First, this case involves only one product, the Silzone heart valve, manufactured by one company, St. Jude. *Cf. In re Ford Motor Co. Vehicle Paint Lit.,* 182 F.R.D. 214, 219-20 (E.D.La.1998) (finding that common issues did not predominate in paint defect action because case did "not involve a single failure event or a simple, fungible product," but a course of conduct over seven years, different vehicles, materials, paints, and manufacturing facilities); *In re American Medical Sys., Inc.,* 75 F.3d 1069, 1085-85 (6th Cir.1996) (holding that common questions did not predominate where plaintiffs' complaints involved multiple products); *Harding v. Tambrands Inc.,* 165 F.R.D. 623, 629-31 (D.Kan.1996) (holding that common questions did not predominate in toxic shock syndrome case where defendants manufactured a number of different styles of tampons); *Yandle v. PPG Indus., Inc.,* 65 F.R .D. 566, 570-71 (E.D.Tex.1974) (holding that common questions did not predominate in asbestos exposure case because plaintiffs were employed over 10-year period, worked in different positions, used varying forms of protection, and were exposed to different concentrations of toxin). Second, as in *Telectronics,* plaintiffs allege only one defect--the inclusion of the Silzone coating on the sewing cuff of St. Jude's heart valves. *See Telectronics,* 172 F.R.D. at 288. *Cf. American Medical Sys.,* 75 F.3d at 1080-81, 1085-85 (holding that common questions did not predominate where plaintiffs did not identify a defect common to all plaintiffs).

Finally, as in *Telectronics,* causation is not "the overarching issue that requires extensive individual proof." *Telectronics,* 172 F.R.D. at 288. The court in that case found that a single course of conduct--the manufacture or design of the device at issue--was probably the reason for the defect and resultant injuries to plaintiffs. *Id.* at 289. In that case, the defendant- manufacturer recalled all of the unimplanted devices. *Id* . Soon after, the FDA found that the device presented an unreasonable danger to the public health. *Id.* The facts in this case are very similar. Here, following information from the AVERT study indicating a higher rate of explantation due to paravalvular leak, St. Jude recalled all of its unimplanted Silzone valves. [FN7] Although the FDA made no proclamation regarding safety of the Silzone valve, several months before the recall, the British equivalent of the FDA, the Medical Devices Agency ("MDA"), issued a warning of possible complications involving the Silzone valve. (*See* Pl.Ex. 21.) Furthermore, both prior to and following the recall, scientific articles and studies were published noting that patients with Silzone valves experienced greater likelihood of complications. (*See, e.g.,* Pl.Ex. 37, 49-50.) Although the facts of this case may not be as conclusive as in *Telectronics,* the circumstances and the evidence produced by plaintiffs convince the Court that the question of causation here is far closer to *Telectronics* than to the cases that St. Jude cites.

> FN7. St. Jude correctly notes that its voluntary recall is no indication of fault or liability. However, it can serve as evidence linking the Silzone valves to problems experienced by valve recipients.

*7 For example, in *Fisher v. Bristol-Myers Squibb Co.,* 181 F.R.D. 365 (N.D.Ill.1998), cited by St. Jude, the court found that individual questions of causation predominated in a case involving drug addiction. *Id.* at 370-71. The court noted that addiction is "not a simple concept" and that demonstrating addiction would "require each plaintiff to provide a substantial amount about his or her medical history, emotional condition, and lifestyle...." *Id.* at 370. Furthermore, the court found that plaintiffs would have to address a huge "variety of potential harms plaintiffs might claim they suffered as a result of using [the drug]," ranging from cardiovascular problems to clinical depression. *Id.*

In *Harding v. Tambrands,* which involved allegations that defendants' tampons caused toxic shock syndrome, the court found that causation would be an overwhelming issue because each defendant marketed a number of different styles of tampons. *Harding,* 165 F .R.D. at 630. Thus, each plaintiff would have to provide evidence of which particular tampon type caused her damages. *Id.*

St. Jude also relies upon *Hurd v. Monsanto Co.,* in which plaintiffs alleged damages from exposure to PCBs over as many as twenty years. *Hurd,* 164 F.R.D. at 237. The court noted that "[u]ndeniably, some class members have been exposed to PCBs for only a few months and at low levels, while others, for decades and at high levels." *Id.* at 240. The court therefore found that individual questions of causation would predominate because the case would require "an individual inquiry into the circumstances involving each class member's exposure and susceptibility." *Id.*

Finally, in *Reilly v. Gould, Inc.,* 965 F.Supp. 588 (M.D.Pa.1997), plaintiffs who lived near a battery crushing and lead processing plant sued the battery company for injuries caused by lead exposure. *Id.* at 593. The court held that "the presence of ... individualized factors affecting individual plaintiffs ... wreaks havoc on the notion that all plaintiffs' injuries have been caused solely by the defendant's actions." *Id.* at 602. The court specifically found that individual questions of causation predominated because there were many other possible sources of plaintiffs' lead exposure besides the defendant's facility. *Id.* at 603-04.

In each of these cases, the individualized questions barring certification all involved the core of issue of the case--plaintiffs' very exposure to the allegedly harmful substances--be it addictive levels of drugs, toxic tampon material, PCBs, or lead. In this case, as in *Telectronics,* there is no question about plaintiffs' exposure to the allegedly harmful device. Every plaintiff received a Silzone valve, and every plaintiff alleges that he or she was harmed, or faces a risk of harm, from that valve. To be sure, individual issues exist in this case, but questions about plaintiff's medical history are not as crucial to this case as is, for example, the level of PCB exposure in a PCB exposure case. The causation

question here is far simpler and unitary than in any of the cases that St. Jude cites, and as in *Telectronics,* is not an overarching issue requiring individual proof. Therefore, the Court finds that common questions predominate in plaintiffs' common law claims.

***8** St. Jude also contends that predominance is not satisfied because individual questions of damages overwhelm common issues. This argument applies primarily to Class II, since all Class I plaintiffs seek the same relief. [FN8] Still, this argument is unavailing. It is well-established that "[n]o matter how individualized the issue of damages may be, these issues may be reserved for individual treatment with the question of liability tried as a class action." *Sterling v. Velsicol Chemical Corp.,* 855 F.2d 1188, 1197 (6th Cir.1988). Thus, the fact that each member of Class II might request separate damages "is not necessarily fatal to class action treatment as long as common questions of law or fact running through each claim predominate." *Haley,* 169 F.R.D. at 651 (citation and internal quotation marks omitted). Because the Court has already determined that common questions of law and fact predominate in plaintiffs' common law claims, variations in damages will not prevent a finding of predominance. *See id. See also Alpern,* 84 F.3d at 1540 (holding that the fact that damage calculations might differ "is a minor matter" when the claims share "fundamental similarities"); *Select Comfort Corp.,* 202 F .R.D. at 610 (noting that "courts frequently grant class certification despite individual differences in class members' damages"); *Telectronics,* 172 F.R.D. at 290 ("The damage issue, although requiring individualized proof, does not preclude class certification."); *Minnesota v. U.S. Steel Corp.,* 44 F.R.D. 559, 571-72 (D.Minn.1968) (holding that individual damage questions will not prevent a finding of predominance).

> FN8. The fact that individual Class I plaintiffs would have monitoring programs tailored to their needs is a question of the program's administration, not one of the character or degree of relief.

b. Superiority

In analyzing superiority, the Court primarily considers "the difficulties likely to be encountered in the management of a class action." Fed.R.Civ.P. 23(b)(3). Here, the main factor affecting superiority involves application of state law to plaintiffs' claims. Even if common questions of law exist, the application of multiple state laws may render the case unmanageable as a class action. Indeed, a number of courts in recent years have held that nationwide state law class actions are unmanageable and cannot be certified. *See, e.g., Andrews v. American Telephone & Telegraph Co.,* 95 F.3d 1014, 1024-25 (11th Cir.1996); *Castano v. American Tobacco Co.,* 84 F.3d 734, 741-44 (5th Cir.1996); *In re Rhone-Poulenc Rorer Inc.,* 51 F.3d 1293 (7th Cir.1995).

St. Jude contends that such is the case here. It argues that because plaintiffs reside in all 50 states, the law of each state must be at least analyzed, and likely applied to the individual cases. St. Jude further contends that because each state has different laws and elements governing negligence, strict liability, breach of warranty, and medical monitoring, common questions of law will not predominate in any nationwide case attempting to apply the law of all 50 states. Plaintiffs contend that it is not necessary to apply the laws of all 50 states, and that the Court should instead apply Minnesota law to the entire case. Given this dispute over which law to apply, the Court must conduct a conflict of laws analysis. [FN9]

> FN9. The Court notes that the minimal constitutional requirements to apply Minnesota law to this action are satisfied. *See Phillips Petroleum Co. v. Shutts,* 472 U.S. 797 (1985). In *Shutts,* the Court held that "for a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Id.* at 818. This Court agrees with plaintiffs that Minnesota has significant contacts by virtue of St. Jude having its headquarters and manufacturing facilities in Minnesota, and because many of the decisions regarding the Silzone valve were made by St. Jude in Minnesota.

*9 Federal courts sitting in diversity apply the forum state's choice-of- law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.,* 313 U .S. 487, 496 (1941); *Nesladek v. Ford Motor Co.,* 46 F.3d 734, 736 (8th Cir.1996). Before proceeding with the choice-of-law analysis, the court must determine that a conflict exists between the laws of the forums under consideration. *Nodak Mutual Ins. Co. v. American Family Ins. Co.,* 604 N.W.2d 91, 93-94 (Minn.2000). Given that the common laws of negligence, strict liability, warranties, and monitoring of all 50 states are potentially implicated, the Court presumes that a true conflict of laws exists. Minnesota has adopted the "significant contacts test" for choice of law analyses. *Id.* at 94; *Nesladek,* 46 F.3d at 738. This test consists of the following choice-influencing factors: (1) predictability of results; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law. *Nodak,* 604 N.W.2d at 94.

The first factor applies primarily to contractual and other "consensual transactions where the parties desire advance notice of which state law will govern in future disputes." *Id.* Minnesota courts have held that the "unplanned nature" of accidents and, by extension, torts, "lessens the importance of predictability of results" in such cases. *Id.* (quoting *Hime v. State Farm Fire & Casualty Co.,* 284 N.W.2d 829, 833 (1979)). Thus, the Court finds that the first factor is not applicable in this tort case.

The second factor, maintenance of interstate order, is primarily concerned with whether application of one state's law "would manifest disrespect" for the sovereignty of the state with conflicting law, or would "impede the interstate movement of people and goods." *Jepson v. General Casualty Co. of Wis.,* 513 N.W.2d 467, 471 (Minn.1994). In tort cases, this factor is satisfied "as long as the state whose laws are purportedly in conflict has sufficient contacts with and interest in the facts and issues being litigated." [FN10] *Nesladek,* 46 F.3d at 739. Given that St. Jude is located in Minnesota and that many decisions regarding the Silzone valves were made in this state, the Court finds that Minnesota has sufficient contacts to the litigation. Thus, this factor favors applying Minnesota law. The third factor, simplification of the judicial task, would also seem to favor application of Minnesota law, because it would be easier to apply the law of one state rather than those of all fifty states.

FN10. This standard is more exacting than the constitutional test of *Shutts. See Nesladek v. Ford Motor Co.,* 46 F.3d 734, 739 (8th Cir.1995) (holding that a state can have sufficient contacts to satisfy *Shutts* but not enough to satisfy the second choice-influencing factor).

The fourth factor, advancement of the forum's governmental interests, is probably the most important. *See id.* at 738 (noting that some Minnesota courts skip the first three factors). Plaintiffs contend that Minnesota's governmental interests favor application of Minnesota law, but plaintiffs' analysis is flawed. Although plaintiffs analyze Minnesota's interests under the choice-influencing factors, they do not compare Minnesota's interests with those of any other state. Minnesota law, however, requires such a side-by-side comparison. *Nesladek,* 46 F.3d at 739 (noting that the governmental interests factor would always favor choice of forum law unless the court considers the relative policy interests of the two states) (quoting *Lommen v. City of East Grand Forks,* 522 N.W.2d 148, 152 (Minn.Ct.App.1994)); *Gate City Fed. Sav. & Loan Ass'n v. O'Connor,* 410 N.W.2d 448, 451 (Minn.1987); *Myers v. Government Employees Ins. Co.,* 225 N.W.2d 238, 242 (Minn.1974). Here, plaintiffs' analysis reveals that they gave serious consideration only to Minnesota's governmental interests, arriving at the conclusory determination that Minnesota law should apply. [FN11]

FN11. The three cases that plaintiffs cite in support of applying Minnesota law provide no help. Choice of law considerations are irrelevant in *In re Lutheran Brotherhood Variable Ins. Prod. Co. Sales Practices Lit.,* 201 F.R.D. 456 (D.Minn.2001), because that case was an action under Minnesota statutes. The other two cases, *Peterson v. BASF Corp.,* 618 N.W.2d 821 (Minn.Ct.App.2000) and *Heller v. Schwan's Sales Enterprises, Inc.,* 548 N.W.2d 287 (Minn.Ct.App.1996) do not help plaintiffs because they contain no

analysis of relevant choice-of-law considerations.

***10** Although Minnesota clearly has significant interests in applying its law to this case, the Court cannot ignore the interests of states in which class members were implanted with Silzone valves. These states' interests go beyond ensuring that their citizens are compensated for alleged damages; the states also have strong interests in applying their relevant laws to the marketing, sale, and implantation of medical devices within their borders. *See In re Diet Drugs Prod. Liability Lit.*, Civ. No. A98-20626, 1999 WL 673066 at *15 (E.D.Pa. Aug. 26, 1999). Given the potential diversity of state laws that apply to both classes, the Court cannot find--and plaintiffs have not demonstrated--that Minnesota's governmental interests are more important than those of other states. *See Nesladek,* 46 F.3d at 749. The Court finds that this crucial factor militates against applying Minnesota law here. Therefore, based upon this analysis of relevant factors, and recognizing the importance of the compared governmental interests, the Court determines that it will apply the law of the state in which each class member's claim arose to the members of the class. [FN12]

FN12. The Minnesota Supreme Court recently held that it has not placed any emphasis on the fifth factor, the better rule of law, for nearly 20 years. *Nodak Mutual Ins. Co. v. American Family Mutual Ins. Co.*, 604 N.W.2d 91, 96 (Minn.2000). This court therefore finds it unnecessary to address this factor.

St. Jude contends that applying the laws of fifty states to these classes would be so complicated as to render the class unmanageable. Although many courts have so held, no case has held that certification of such classes is *per se* impossible. *See, e.g., In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016-18 (7th Cir.2002) (holding that application of laws of all 50 states renders class unmanageable); *Andrews,* 95 F.3d at 1024-25 (same); *Castano,* 84 F.3d at 741-44 (same); *Rhone-Poulenc,* 51 F.3d at 1293 (same).

At least one court has addressed such variations in state law by the creation of subclasses that group similar state laws together. *See Telectronics,* 172 F.R.D. at 290-94 (certifying nationwide negligence, strict liability, and medical monitoring classes). This method would eliminate the problem of instructing one jury on the laws of all fifty states, while still retaining the efficiencies of the class action procedure and fulfilling the collective-action purpose of Rule 23. *See generally,* Comment, Ryan Patrick Phair, *Resolving the "Choice-of-Law Problem" in Rule 23(b)(3) Nationwide Class Actions,* 67 U. Chi. L.Rev. 835, 851 (Summer 2000) . To create appropriate subclasses, the Court will have to evaluate which variations in state law are "important or substantial enough to preclude class certification or require subclasses." *Telectronics,* 172 F.R.D. at 292. For "while it is certainly true that state tort law varies, the question under the superiority prong of Rule 23(b)(3) is can the relevant variations be dealt with in a simple and efficient manner." *Id.* The Court finds that the superiority requirement can be met, and certification granted under Rule 23(b)(3) to various subclasses of the relevant causes of action. "[I]f the elements of the cause of action are the same and the legal standards on 'important/meaningful/significant/pivotal' issues are substantially similar, the state laws can be grouped for purposes of class certification." *Id.* The Court envisions a minimal number of subclasses, and will find that only significant variations in state law will be sufficient to require different subclasses.

***11** It is evident from the parties' briefs that they did not focus on the possibility of certifying subclasses. Therefore, the Court will request briefing from the parties on what minimum number and type of subclasses would be appropriate for plaintiffs' negligence, strict liability, breach of warranty, and monitoring claims. However, the Court now finds that common issues of fact and law predominate for both proposed classes, and conditionally finds that a class action is the superior method of adjudicating the claims of both classes. Therefore, the Court will conditionally certify plaintiffs' common law claims for both classes pursuant to Rules 23(b)(3) and (c)(4). [FN13]

FN13. Rule 23(c)(4) gives the court authority to divide a proposed class into subclasses. *See* Fed.R.Civ.P. 23(c)(4).

2. Rule 23(b)(2)--Monitoring Class Only

St. Jude challenges certification of Class I under Rule 23(b)(2) on three grounds. First, that plaintiffs do not have constitutional standing to bring a monitoring claim. Second, that monitoring is not an injunctive remedy and is therefore unavailable under Rule 23(b)(2). Finally, St. Jude contends that diverse issues of state law undermine the cohesiveness of the class and prevent certification.

a. Article III Standing

St. Jude first argues that the monitoring plaintiffs do not satisfy the constitutional requirements for standing under Article III of the U.S. Constitution. Plaintiffs bear the burden of establishing that they have standing to bring the claim for medical monitoring. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 559-60 (1992). This constitutional prerequisite must be met before a class certification inquiry can commence because it determines the Court's very power to hear the case. *Rivera v. Wyeth-Ayers Laboratories,* 283 F.3d 315, 319 (5th Cir.2002). To demonstrate standing under Article III, plaintiff must satisfy three elements: (1) an "injury-in-fact;" (2) a causal connection between such injury and St. Jude's conduct; and (3) a likelihood that a favorable decision will redress the injury. *Defenders of Wildlife,* 504 U.S. at 560-61.

When analyzing standing at the class certification stage, the Court assumes the truth of facts alleged by the plaintiff. *Id.; Eisen v. Carlisle & Jacquelin,* 417 U.S. 156, 178 (1974) (holding that preliminary inquiry into merits of the case is not proper at class certification stage). *See In re Propulsid Prod. Liability Lit.,* 208 F.R.D. 133, 139 (E.D.La.2002) (noting that the standard is similar to that used under Fed.R.Civ.P. 12(b)(6)).

St. Jude contends that plaintiffs do not have standing because they have not suffered an injury-in-fact. Such an injury must be concrete and particularized, and it must be actual or imminent, not conjectural or hypothetical. *Defenders of Wildlife,* 504 U.S. at 560. Furthermore, the injury may not be to a mere cognizable interest, but plaintiffs must show that they were themselves among the injured. *Sierra Club v. Morton,* 405 U.S. 727, 734-35 (1972).

St. Jude specifically argues that plaintiffs alleged "subclinical" injuries stemming from the implant of Silzone valves is not a sufficient basis for injury-in-fact under Article III. Although the parties dispute whether the Silzone valves will have a permanent or long-term hazardous effect on implanted patients, at this early stage in the litigation the Court finds that Class I plaintiffs have satisfied their burden. Specifically, plaintiffs have alleged and provided evidence that the Silzone valve places them at increased risk of paravalvular leak and other complications. [FN14] "[C]ourts have long recognized that an increased risk of harm ... is an injury in fact." *Propulsid,* 108 F.R.D. at 139. *See Friends For All Children, Inc. v. Lockheed Aircraft Corp.,* 746 F.2d 816, 826 (D.C.Cir.1984) (holding that the need for medical monitoring constitutes an injury-in-fact when the need is "supported by testimony of competent medical experts"); *In re Paoli R.R. Yard PCB Lit.,* 916 F.2d 829, 849-52 (3d Cir.1990) (holding that medical monitoring action can be premised upon proof of exposure to hazardous substances resulting in the potential for injury). *Cf. Rivera,* 283 F.3d at 319 (holding that plaintiffs had not established injury-in-fact where they claimed mere economic injury and did not allege that drug had any future health consequences). The Court finds that plaintiffs have adequately supported their allegations of "monitoring injury," and therefore that they satisfy the injury- in-fact standard. (*See* Abramson Dec., Pl.Ex. 28; Tyers Dec., Pl.Ex. 37.) *See also Friends For All Children,* 746 F.2d at 826 (describing a person's "interest in avoiding expensive diagnostic examinations").

FN14. Plaintiffs have submitted testimony by medical experts supporting their claim for medical monitoring. (*See, e.g.,* Abramson Dec., Pl.Ex. 28; Tyers Dec., Pl.Ex. 37.) The admissibility of some of this evidence was extensively debated prior to the hearing on class certification. The Court, in denying plaintiffs' motion to exclude St. Jude's objections to their medical expert testimony, ruled that a full analysis of the medical expert evidence under *Daubert v. Merrill Dow Pharmaceuticals,* 509 U.S. 579 (1993), is not appropriate at this time. (*See* 6/25/02 Status Conference Tr. at 30.) Nevertheless, the Court has carefully scrutinized plaintiffs medical evidence to determine

whether it supports class certification. *See Bacon v. Honda of America Mfg., Inc.,* 205 F.R.D. 469-71 (S.D.Ohio 2001). Keeping in mind that at this stage plaintiffs need only properly allege and support their claim, not prove it, *Eisen v. Carlisle & Jacquelin,* 417 U.S. 156, 178 (1974), the Court has avoided conducting a lengthy substantive analysis of plaintiffs' experts, ensuring only that "the basis of the expert opinion[s are] not so flawed that [they] would be inadmissible as a matter of law." *In re Visa Check/Mastermoney Antitrust Lit.,* 280 F.3d 124, 135 (2d Cir.2001).

***12** St. Jude does not dispute that plaintiffs have satisfied the remaining two requirements for Article III standing, and the Court finds that they have been satisfied. Causation is satisfied because plaintiffs have alleged an injury--the need for medical monitoring--that is fairly traceable to St. Jude's marketing and selling the Silzone valves that were implanted in them, which plaintiffs claim are defective. *See Propulsid,* 208 F.R.D. at 139. The Court also finds that enacting a medical monitoring and research program would likely redress plaintiffs' alleged injuries--namely, a need for monitoring due to increased risk of complications. Therefore, the Court concludes that Class I plaintiffs have standing to pursue their medical monitoring claim. [FN15]

FN15. St. Jude also argues that there is a "lack of need" for plaintiffs' requested medical monitoring, and even suggests that the proposed monitoring may itself be dangerous. (*See* Def. Opp. Br. at 60-62.) The Court finds that this question involves the merits of plaintiffs' claim, and is therefore not appropriate to consider at the class certification stage. *See Eisen,* 417 U.S. at 178.

b. Monitoring--Injunctive or Legal Relief?

Plaintiffs may be eligible for relief under Rule 23(b)(2) when the party opposing certification has acted or refused to act on grounds generally applicable to the class. Fed.R.Civ.P. 23(b)(2); *DeBoer,* 64 F.3d at 1175. St. Jude contends that Class I may not be certified under this rule because plaintiffs do not seek equitable relief. Class certification under Rule 23(b)(2) is only appropriate where the primary relief sought is declaratory or injunctive, and certification is unavailable where the "principal relief sought is money damages." *Haley,* 169 F.R.D. at 647. [FN16] St. Jude claims that because the proposed medical monitoring trust fund would be paid for by St. Jude, the medical monitoring claim is equivalent to one for money damages.

FN16. The Advisory Committee Note to Rule 23(b)(2) explicitly states that the rule "does not extend to cases in which the appropriate final relief relates exclusively or predominately to money damages." Fed.R.Civ.P. 23(b)(2) Adv. Comm. Note.

In this case, plaintiffs do not ask St. Jude to pay a sum of money, nor do they request an order directing St. Jude to pay their medical expenses directly. *See Day v. NLO, Inc.,* 144 F.R.D. 330, 335 (S.D.Ohio 1992), *vacated on other grounds, In re NLO,* 5 F.3d 154 (6th Cir.1993). Rather, plaintiffs ask the Court to establish a medical monitoring program that is managed by the Court and in which the medical data is utilized for group studies. Just because St. Jude--if found liable--would have to pay for such relief does not eliminate the injunctive nature of this remedy. *See id.* at 336. *See also In re NLO,* 5 F.3d at 159 (holding that medical monitoring claims are generally injunctive in nature).

Both parties claim support from *Werlein v. United States,* 746 F.Supp. 887 (D.Minn.1990), *vacated in part on other grounds,* 793 F.Supp. 898 (D.Minn.1992). *Werlein,* however, makes clear that the relief plaintiffs seek here is injunctive. In that case, plaintiffs sought an order forcing defendants "to pay a lump sum of cash into a fund, and ... persons eligible for medical monitoring [would] use that pot of cash to obtain reimbursement" for their medical screenings. *Id.* at 895. The court held that this proposed fund was nothing "besides an exchange of money," and therefore could not be authorized as injunctive relief. *Id.* In this case, however, plaintiffs propose no "pot of cash" and no reimbursements. Rather, they propose a unified monitoring program administered by the Court and

paid for by a trust funded by St. Jude. The program also has provisions for research, epidemiological studies, and information sharing. The *Werlein* court recognized that "where a number of persons are exposed to a toxin about which little is known, and it is necessary to gather and share information regarding diagnosis and treatment through screening, the Court would consider framing a medical monitoring and information sharing program as injunctive relief." *Id.* Such are the circumstances in this case. Plaintiffs allege that the silver coating on the Silzone valves has increased the risk of injury to the members of Class I, and their proposed monitoring program includes research and information sharing components. Thus, the Court finds that *Werlein* supports the conclusion that plaintiffs' monitoring claim seeks equitable relief and may therefore be certified under Rule 23(b)(2). *See Craft v. Vanderbilt Univ.*, 174 F.R.D. 396, 406-07 (M.D.Tenn.1996) (holding that an action for court-supervised medical monitoring qualifies as injunctive under Rule 23(b)(2)); *Yslava v. Hughes Aircraft Co.*, 845 F.Supp. 705, 713 (D.Ariz.1993) (same).

***13** Despite the equitable nature of medical monitoring, plaintiffs' monitoring claim would still be inappropriate under Rule 23(b)(2) if plaintiffs also sought such significant monetary relief that the equitable monitoring claim became merely "incidental to the larger claims for damages." *In re Copley Pharmaceutical, Inc.*, 158 F.R .D. 485, 490-91 (D.Wyo.1994). *See Allison v. Citgo Petroleum Corp .*, 151 F.3d 402, 415 (5th Cir.1998) . In this case, however, Class I plaintiffs seek primarily injunctive relief. The only portion of Class I's complaint that seeks monetary damages is the claim for restitution under Minnesota's consumer protection laws. (*See* Complaint ¶ 78.) Although this count seeks a refund of money paid for Silzone products and certain consequential damages, it nevertheless is clear from the record and the pleadings that plaintiffs' major concern is whether the Silzone-coated valves are defective. *See In re Telectronics Pacing Systems, Inc., Accufix Atrial "J" Leads Prod. Liability Lit.*, 164 F.R.D. 222, 229 (S.D.Ohio 1995) (certifying a class under Rule 23(b)(2) where plaintiffs sought monetary and injunctive relief, but plaintiffs' "major concern" addressed whether medical device was defective). In *Haley*, the court refused to certify a monitoring class under Rule 23(b)(2) where the action "was not brought with the purpose of identifying whether the [medical devices] in question were defective or not, like the court in *Telectronics* assumed ... but to recover from defendant for selling these defective [devices]." *Haley*, 169 F.R.D. at 657. The present case is like *Telectronics*, in that plaintiffs seek primarily a monitoring and epidemiological program; the crux of their action is not money damages or treatment of future illness. *See Zinser v. Accufix Research Institute, Inc.*, 253 F.3d 1180, 1195-96 (9th Cir.2001), *superceded on other grounds*, 273 F.3d 1266 (denying certification of monitoring class where plaintiffs sought a fund that would pay for future medical treatment, plus other compensatory and punitive damages). Indeed, in the majority of cases that St. Jude cites in opposing 23(b)(2) certification, the plaintiffs also sought significant monetary damages. *See Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601, 610-11 & n. 10 (W.D.Wash.2001) (denying certification of monitoring class where the plaintiff's desired relief "always focused on damages and a fund of money," and where plaintiff sought no research or information sharing program); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 529 (N.D.Ill.1998) (denying certification of medical monitoring claim where plaintiffs' requested damages for emotional distress, fraud, refund, punitive and exemplary damages showed that the "crux of the action [was] for money damages"); *Smith v. Brown & Williamson Tobacco Corp.*, 174 F.R.D. 90, 100 (W.D.Mo.1997) (refusing to certify class under 23(b)(2) where plaintiff's "many other claims for monetary relief demonstrate[d] that monetary relief is the predominate relief sought"). Because Class I plaintiffs primarily seek to implement a court-supervised program requiring ongoing, elaborate medical monitoring, and do not seek money damages, the Court finds that the requested relief is predominantly injunctive. [FN17]

FN17. Plaintiffs' briefs and oral presentations sought medical monitoring only for Class I. The master complaint, however, appears to seek monitoring for Class II, the "injury class." For the reasons discussed above, Class II cannot be certified under Rule 23(b)(2). It is clear from the entire record and plaintiffs' presentations that Class II seeks primarily compensatory money damages, and that these clams predominate over any medical monitoring or other injunctive relief. *See*

Allison v. Citgo Petroleum Corp., 151 F.3d 402, 415 (5th Cir.1998). Therefore, to the extent that plaintiffs seek certification of Class II pursuant to Rule 23(b)(2), that certification will be denied.

c. Cohesiveness of Proposed Class

***14** St. Jude next contends that even if plaintiffs satisfy the requirements for injunctive relief, the proposed monitoring class may not be certified because it is not cohesive. Although Rule 23(b)(2) has no predominance or superiority requirements, the rule does include "an implicit 'cohesiveness' requirement, which precludes certification when individual issues abound." *Thompson,* 189 F.R.D. at 557. *See Barnes v. American Tobacco Co .,* 161 F.3d 127, 143 (3d Cir.1998); *In re Rezulin Prod. Liability Lit.,* 210 F.R.D. 61, 75 (S.D.N.Y.2002); *Diet Drugs,* 1999 WL 673066 at *14 (noting that Rule 23(b)(2) requires that "the class be entitled to the same relief"). This requirement recognizes that "the claims contemplated in a(b)(2) action are class claims, claims resting on the same grounds and applying more or less equally to all members of the class." *Holmes v. Continental Can Co.,* 706 F.2d 1144, 1155 (11th Cir.1983) (emphasis original). This assumed cohesiveness is one basis for the less stringent requirements of Rule 23(b)(2), which does not generally require individual notice and does not permit members to opt out of the lawsuit. *Id.; Allison,* 151 F.3d at 413- 14.

St. Jude primarily contends that there are too many individual factual and other issues among the members of the monitoring class, and that these differences destroy any common interest across the class. Although St. Jude is correct that a raft of individual issues can destroy a class's cohesiveness, St. Jude focuses here on superficial factual differences between the class members, while the cases it cites emphasize the nature of the relief sought. "The underlying premise of the (b)(2) class--that its members suffer from a common injury properly addressed by class-wide relief'begins to break down when the class seeks to recover ... forms of monetary relief to be allocated based on individual inquiries." ' *Allison,* 151 F.3d at 413 (quoting *Eubanks v. Billington,* 110 F.3d 87, 95 (D.C.Cir.1997). Courts have thus suggested that individual issues destroy cohesiveness primarily when parties assert monetary claims, which require individual factual determinations and therefore mandate "enhanced procedural safeguards to protect the individual rights of class members." *Allison,* 151 F.3d at 413. *See Lemon v. International Union of Operating Engineers, Local No. 139, AFL-CIO,* 216 F.3d 577, 580 (7th Cir.2000) ("A suit for money damages, even if the plaintiffs seek uniform, class-wide equitable relief as well, jeopardizes [the] presumption of cohesion ... because individual claims for compensatory or punitive damages typically require judicial inquiry into the particularized merits of each individual plaintiff's claim."). In this case, as discussed above, plaintiffs' action for medical monitoring is injunctive in nature, and the Court has determined that any claim for monetary relief is merely incidental. Therefore, because individual questions of monetary relief will not arise for Class I, its cohesiveness is not impaired.

***15** St. Jude does note that even if the requested relief is injunctive, individual factual questions may abound that would destroy cohesiveness. St. Jude particularly relies upon two smoking-related actions, *Barnes v. American Tobacco Company* and *Thompson v. American Tobacco Company.* In both of these cases, courts held that an abundance of individual issues destroyed the cohesion of proposed (b)(2) classes. *See Barnes,* 161 F.3d at 143; *Thompson,* 189 F.R.D. at 557. Neither of these cases is analogous here, however. Both *Barnes* and *Thompson* dealt with complicated issues of nicotine addiction and smoking-related illnesses. *See Barnes,* 161 F.3d at 143; *Thompson,* 189 F.R.D. at 553-54. In this case, the monitoring class does not present similar complex issues.

Although the factual issues do not present sufficient individual questions that would defeat cohesiveness, as with the Rule 23(b)(3) analysis, the Court must also address the issue of variance in state law. St. Jude notes that not all states have recognized medical monitoring as an independent cause of action, and that those states that have recognized such an action have varying legal elements. St. Jude contends that this variation also undermines cohesiveness, barring certification of the monitoring class under Rule 23(b)(2).

Plaintiffs argue that Minnesota would join an emerging majority of states in adopting the medical monitoring elements outlined by the Pennsylvania Supreme Court in *Redland Soccer Club v.*

Department of the Army, 696 A.2d 137 (Pa.1997). *See Barnes,* 161 F.3d at 138-39, 146 (applying the *Redland* elements). Implicit in this argument is plaintiffs' contention that Minnesota law alone should apply to the monitoring claim. As discussed in the context of Rule 23(b)(3), however, this Court cannot simply apply the law of one particular state without regard to whether a given class member's claim arises in a jurisdiction that recognizes such a legal theory, or what the elements for such a theory may be. *See Diet Drugs,* 1999 WL 673066 at *14. The Court must consider that some jurisdictions do not even recognize a cause of action for medical monitoring, while others have varying requirements for such a claim. The court in *Diet Drugs* faced a similar situation, and recognized that a real conflict exists between laws modeled on the *Redland* elements, which plaintiffs propose for this case, and other states which, for instance, may require evidence of physical injury for a monitoring claim. *See id.* at *15 (citing Louisiana's law barring plaintiffs who cannot demonstrate a "manifest physical or mental injury or disease" from recovering for a medical monitoring claim).

Here, as in *Diet Drugs,* the Court must first undertake a Minnesota choice- of-law analysis to determine whether Minnesota law (or plaintiffs' prediction thereof) or the laws of all fifty states would apply to the medical monitoring claim. As discussed previously in the Court's Rule 23(b)(3) analysis, the "advancement of the forum's governmental interests" is the most significant choice-influencing factor. *See Nodak,* 604 N.W.2d at 94 (applying Minnesota's choice of law rules); *Nesladek,* 46 F.3d at 738-41(same). The Court is mindful, however, that other states have consciously developed different standards for medical monitoring, or have not adopted such an action at all. These states' interests in applying their laws to the medical device industry within their borders is at least as strong as Minnesota's interest in doing so. *See Diet Drugs,* 1999 WL 673066 at *15. Therefore, the Court again finds that Minnesota's governmental interests do not outweigh those of other states, and the Court will apply the law of the state in which each class member's claim arose to all members of the monitoring class.

***16** St. Jude argues that such diversity of state law destroys the cohesiveness of the monitoring class and bars certification under Rule 23(b)(2). *See Rezulin,* 210 F.R.D. at 75 (holding that variation in state law on monitoring prevented certification). *Rezulin,* a drug case, involved many complicated facts, "as class members took [the drug] at different times, for different periods, in different amounts, and while undergoing different levels of ... health monitoring." *Id.* at 66. Another drug case, however, *Diet Drugs,* held that these challenges are not insurmountable. *Diet Drugs,* 1999 WL 673066 at *16. In that case, "the class members' ingestion of the Diet Drugs was discrete and ascertainable[, and the] dates, duration and amounts of ingestion and the combination of drugs ingested [could] be confirmed through the use of fact sheets and medical records." *Id.* at *15. The present case involves a discrete and ascertainable number of valve recipients. It is known exactly how long each person had the Silzone valve and the circumstances of the implant. These facts are more readily ascertainable than the drug-related information in *Diet Drugs,* and certainly more so than in *Rezulin.* [FN18] The *Diet Drugs* court determined that applying the laws of 50 states to a 23(b)(2) class action does not destroy cohesiveness of the class and does not necessarily render the class unmanageable. *Id.* at *16. The court instead determined that the case could be managed by creating subclasses "dependant on whether the elements of medical monitoring or the underlying legal action significantly differ." *Id.* The court in *Propulsid* recognized this approach, but could not grant conditional certification because Fifth Circuit law does not permit it. This Court is aware of no similar prohibition in the Eighth Circuit. This Court accordingly finds the approach in *Diet Drugs* both persuasive and appropriate in the present case. [FN19] As with the classes under Rule 23(b)(3), the Court will therefore conditionally certify the monitoring class pursuant to Rules 23(b)(2) and (c)(4).

FN18. As with its argument about injunctive relief, St. Jude primarily relies here upon tobacco cases, which involve issues of nicotine addiction and smoking-related illnesses. *See Barnes v. American Tobacco Co.,* 161 F.3d 127 (3d Cir.1998); *Thompson v. American Tobacco Co.,* 189 F.R.D. 554 (D.Minn.1999). These issues, however, are even less susceptible to class treatment and are more likely to destroy cohesiveness. *See In re Diet Drugs Prod. Liability Lit.,*

Civ. No. A. 98-20626, 1999 WL 673066 (E.D.Pa. Aug. 26, 1999) (describing how extreme factual variations undermine cohesiveness in tobacco litigation). The facts of this case are far more certain, and therefore these tobacco cases do not undermine certification of the monitoring class.

FN19. As in *Diet Drugs,* the Court envisions that Class I will be broken down into at least two sub-groups of plaintiffs: those who are asymptomatic but who may have some injury that is presently unknown, and those who have some known injury (that has not yet required explantation) but who have not filed a personal injury claim. Also as in *Diet Drugs,* a consequence of this sub-classing is that class members who are asymptomatic and whose claims arise in jurisdictions that require injury for a tort action to proceed will have to be excluded from the class entirely. *See id.* at *16.

As discussed in the Rule 23(b)(3) analysis, the Court finds that the parties have not sufficiently addressed the question of how the Court would manage a class action with subclasses grouped according to categories of varying state laws. Therefore, the Court will require such briefing according to a schedule determined after discussion with counsel. As in the *Diet Drugs* case, the court anticipates creating subclasses based upon the variance of both medical monitoring law and variances in the underlying claims of strict liability, negligence, and breach of warranties, for which monitoring serves as a remedy in some jurisdictions. *See id.* at *17.

3. Rule 23(b)(1)(A)--Monitoring Class Only

Plaintiffs also seek certification of the monitoring class pursuant to Rule 23(b)(1)(A). This rule provides for class certification when separate actions would create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for the party opposing the class. Fed.R.Civ.P. 23(b)(1)(A). The rule is designed to avoid situations where different results in separate actions would impair the opposing party's ability to pursue a uniform continuing course of conduct. *Telectronics,* 172 F.R.D. 271, 284 (S.D.Ohio 1997) (quoting 7A Charles A. Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice & Procedure: Federal Rules of Civil Procedure* § 1773 (2d ed.1986)).

***17** The Court finds that this case is not suitable for certification under Rule 23(b)(1)(A) because plaintiffs are not suing for different or incompatible relief. *See Fogie v. Rent-A-Center,* 867 F.Supp. 1398, 1403 (D.Minn.1993) (holding that certification under 23(b)(1)(A) is not appropriate where plaintiffs do not seek incompatible relief). Although a monitoring program may be tailored differently to various members of Class I, these are matters of program administration, and do not affect the character or the relief that Class I seeks. Furthermore, Rule 23(b)(1)(A) was designed to protect the party opposing certification--here, St. Jude--and at least one decision in this District has found that a defendant waives protection of the rule by opposing certification. *Id. See 5 Moore's Federal Practice* § 23.40. Here, St. Jude opposes certification under 23(b)(1)(A). For these reasons, the Court concludes that the monitoring class should not be certified under that rule.

B. Minnesota Consumer Protection & Deceptive Trade Practices Statutes

Finally, plaintiffs seek certification of both classes for violations of Minnesota statutes governing false statements in advertising, Minn.Stat. § 325F.67, unlawful consumer practices, Minn.Stat. § 325F.69, and deceptive trade practices, Minn.Stat. § 325D.44 . St. Jude argues that Minnesota law should not presumptively apply to all class members, and that even if it did, plaintiffs must demonstrate individual reliance in each case. These two factors, St. Jude contends, would overwhelm any common issues and make a class action unmanageable.

First, St. Jude argues that plaintiffs cannot presume that Minnesota law applies to all class members, who are citizens of various states. As it did in the 23(b)(2) and (b)(3) contexts, St. Jude contends that plaintiffs--and this Court--must undertake a state-by-state analysis to determine which law applies. Such an exhaustive inquiry, St. Jude claims, would "swamp" any common issues and make either class impossible to certify. Although these arguments affected the Court's analysis of common

law claims under Rules 23(b)(2) and (b)(3), they do not apply with equal force here. This is because in contrast with plaintiffs' common law claims of negligence, strict liability, monitoring, and breach of warranty, these claims are brought under specific provisions of Minnesota's consumer protection and deceptive trade practices statutes.

The District of Minnesota addressed this precise question in the *Lutheran Brotherhood* case. In that case, plaintiffs sought certification under Rule 23(b)(3) for alleged violations of a provision of Minnesota's consumer protection statute. [FN20] *See Lutheran Brotherhood,* 201 F.R.D. at 460- 64. The court rejected the contention that there were any impediments to applying Minnesota's consumer protection statutes to a nationwide class, noting that these statutes explicitly permit "any person" injured by violations of the statutes to bring suit. *Id.* at 461 n. 1.

FN20. The statute was Minn.Stat. § 325F.69, which plaintiffs also allege in this case.

***18** This holding is foursquare with the present case. Plaintiffs' claims under provisions of Minnesota's consumer protection statute, Minn.Stat. §§ 325F.67 and 325F.69, find support in another provision of Minnesota law that permits "any person" injured by a violation of these statutes to bring suit. Minn.Stat. § 8.31, subd. 3a. As the Minnesota Supreme Court held in *Group Health Plan, Inc. v. Philip Morris Inc.,* 621 N.W.2d 2 (Minn.2001), none of these statutes contain any language restricting who may sue for violation of the consumer protection laws. *Id.* at 8. Likewise, plaintiffs' claims under Minnesota's Uniform Deceptive Trade Practices Act, Minn.Stat. § 325.D44, are authorized by a provision of that law permitting "a person likely to be damaged" by a deceptive trade practice to seek injunctive relief. Minn.Stat. § 325D.45, subd. 1 (emphasis added). [FN21] In the present case, it is clear that plaintiffs meet these definitions of "any person" or "a person," and may therefore bring suit under Minnesota law. The fact that individual plaintiffs hail from other states is immaterial. [FN22] Plaintiffs seek relief under particular Minnesota statutes. In the absence of evidence that plaintiffs do not have standing to sue--and St. Jude provides none--the Court finds no reason to deny plaintiffs their chosen claim of action. Minnesota law may therefore apply to the classes' consumer protection and deceptive trade practices allegations.

FN21. St. Jude correctly notes that relief under the deceptive trade practices act ("DTPA"), Minn.Stat. § 325D.44, is limited to injunctive remedies. *See Tuttle v. Lorillard Tobacco Co.,* Civ. No. 99-1550, 2001 WL 821831 at *4 (D.Minn. July 5, 2001) (stating that "courts have uniformly held that the sole remedy for violations of the DTPA is injunctive relief," and citing cases). This count of plaintiffs' complaint seeks both monetary relief and injunctive relief, in the form of monitoring. The Court will therefore construe the § 325D.44 allegations as applying only to the request for monitoring.

FN22. To the extent St. Jude argues that applying Minnesota law to the classes is unconstitutional, the Court disagrees. To apply Minnesota law here in a constitutional manner, the Court must find only that Minnesota has "a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Phillips Petroleum Co. v. Shutts,* 472 U.S. 797, 818 (1985); *Lutheran Brotherhood,* 201 F.R.D. at 461 n. 1. Here, as the Court has discussed, the parties--especially the defendant, St. Jude--have at least a significant contact with Minnesota. St. Jude is headquartered in Minnesota and according to plaintiffs, "much of the conduct relevant to the statutory consumer fraud claims occurred in or emanated from Minnesota." *See Lutheran Brotherhood,* 202 F .R.D. at 461 n. 1. Therefore, the Court finds that Minnesota has a significant interest in this litigation, and that application of its law is neither arbitrary nor fundamentally unfair.

Second, St. Jude argues that even if Minnesota law does apply, common questions will not predominate because each individual plaintiff must prove

reliance under Minnesota's consumer protection statute. This proposition directly contradicts Minnesota law. It is by now well established that plaintiffs need not establish reliance when seeking injunctive relief under Minnesota's consumer fraud and deceptive trade practices statutes. *Thompson,* 189 F.R.D. at 552-53 (construing the same statutes at issue in this case, Minn.Stat. §§ 325D.44, 325F.67, and 325F.69). More recently, the Minnesota Supreme Court broadened the scope of statutory claims under these statutes in *Group Health,* holding that a plaintiff need not plead individual consumer reliance on a defendant's wrongful conduct to state a claim for damages. *Group Health,* 621 N.W.2d at 12; *Lutheran Brotherhood,* 201 F.R.D. at 462-63. Rather, plaintiffs seeking damages need only establish a "causal nexus between their damages and the defendant's wrongful conduct." *Group Health,* 621 F.R.D. at 14; *Lutheran Brotherhood,* 201 F.R.D. at 463.

In this case, the Court finds that plaintiffs have pleaded and presented evidence that their damages stem at least in part from St. Jude's marketing material that, according to plaintiffs, claimed that Silzone effectively prevented endocarditis. (*See, e.g.,* Pl.Ex. 59-60.) Plaintiffs have also demonstrated that these common issues of fact predominate over individual issues, as do the common questions of law regarding St. Jude's alleged violation of Minnesota's consumer protection and deceptive trade practices statutes. The Court also finds that given the common issues and the fact that proof of reliance is unnecessary, class action treatment is a superior mechanism for resolving these claims. Accordingly, the Court finds that plaintiffs' consumer protection claims may be certified as class actions under Rule 23(b)(3) for both Class I and Class II.

CONCLUSION

***19** The Court finds that both proposed classes meet the threshold requirements of Rule 23(a). Furthermore, the Court finds that common issues of law and fact predominate in both classes, and that a class action is likely the superior way to adjudicate the claims of both classes. Therefore, the Court conditionally certifies plaintiffs' common law claims for both Class I and Class II pursuant to Rule 23(b)(3). Likewise, the Court conditionally finds that Class I is cohesive, and conditionally certifies the monitoring class pursuant to Rule 23(b)(2). The Court further determines that separate actions would not create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for St. Jude, and therefore refuses to certify Class I pursuant to Rule 23(b)(1)(A). Finally, the Court determines that common issues of law and fact predominate in plaintiffs' claims under Minnesota's consumer protection and deceptive trade practices acts, and that a class action is the superior method of adjudicating those claims. Therefore, the Court certifies plaintiffs' claims under those statutes pursuant to Rule 23(b)(3).

ORDER

Based on the foregoing, all the records, files, and proceedings herein, IT IS HEREBY ORDERED that plaintiffs' Motion for Class Certification [Docket No. 49] is GRANTED IN PART and DENIED IN PART as detailed in the "Conclusion" section of the Memorandum Opinion accompanying this Order.

2003 WL 1589527 (D.Minn.)

END OF DOCUMENT

Not Reported in F.Supp.2d
(Cite as: 1999 WL 673066 (E.D.Pa.))

United States District Court, E.D. Pennsylvania.

In re DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION.
Barbara JEFFERS and Johnna Day, on behalf of themselves and all others similarly situated
v.
AMERICAN HOME PRODUCTS CORPORATION.
THIS DOCUMENT RELATES TO ALL ACTIONS.

No. CIV. A. 98-20626.

Aug. 26, 1999.

MEMORANDUM AND PRETRIAL ORDER NO. 865

LOUIS C. BECHTLE, J.

***1 END OF FRONT MATTER**

Presently before the court are plaintiffs Barbara Jeffers' ("Jeffers") and Johnna Day's ("Day") (collectively "Plaintiffs") Motions for Class Certification Pursuant to Federal Rule of Civil Procedure 23(b)(2) and Motion to Amend the Complaint and defendant American Home Products Corporation's ("AHP") responses thereto. For the reasons set forth below, the court will conditionally certify a medical monitoring class as follows.

I. *BACKGROUND*

First, the court will review the history of the pharmaceutical products that are the subject of this civil action. Second, the court will review the history of the Diet Drug Litigation [FN1] and MDL No. 1203 generally. Third, the court will review the procedural history of the *Jeffers* civil action.

FN1. The court will use the term "MDL No. 1203" to refer to the consolidated federal cases before it, captioned as *In re: Diet Drugs (phentermine, fenfluramine, dexfenfluramine) Products Liability Litigation*. The court will use the term "Diet Drug Litigation" when referring to the federal and state cases collectively.

A. *The Diet Drugs*

The Diet Drug Litigation involves three prescription pharmaceutical products--phentermine, fenfluramine and dexfenfluramine (collectively, the "Diet Drugs")--which were approved by the Food and Drug Administration ("FDA") for use as appetite suppressants. (Stip. 1/5/99 ¶ 1.) Phentermine was approved by the FDA in 1959. [FN2] (Pls.' Mot. for Cert. at 7 n.2.) Fenfluramine was approved for use in 1973 and, between December 1989 and September 15, 1997, AHP, directly and/or through its subsidiaries, labeled and sold fenfluramine under the brand name Pondimin. (Pls.' Mot. for Cert. at 7; Stip. 1/5/99 ¶ ¶ 2 & 5.) Dexfenfluramine was approved in 1996 and, between June 1996 and September 15, 1997, AHP, directly and/or through its subsidiaries, promoted, marketed, labeled and sold dexfenfluramine under the brand name Redux. (Pls.' Mot. for Cert. at 8; Stip. 1/5/99 ¶¶ 3 & 5.) Fenfluramine and dexfenfluramine are chemically related. (Pls.' Mot. for Cert. at 7.) Estimates set the number of persons ingesting Pondimin at four million and the number of persons ingesting Redux at two million. (Stip. 1/5/99 ¶ 6; Pls.' Mot. for Cert. at 8-9 & Ex. 3; Tr. 3/17/99 at 9.)

FN2. Phentermine continues to have FDA approval and is currently sold as a "generic" drug by a number of manufacturers.

Plaintiffs allege that sales of Redux and Pondimin increased dramatically between 1992 and 1996, following a study published in May 1992 that analyzed the use of Pondimin in combination with phentermine and concluded that the combination of drugs, commonly called "Fen/Phen," facilitated weight loss. (Pls.' Mot. for Cert. at 7.) However, subsequent studies linked the use of the Diet Drugs to a number of health problems. For example, a

study published in August 1996 in the New England Journal of Medicine concluded that the ingestion of fenfluramine and dexfenfluramine increased the incidence of Primary Pulmonary Hypertension ("PPH"), a rare and often fatal disease. (Stip. 1/5/99 ¶ 8, Ex. A.) Another study published in July 1997, also in the New England Journal of Medicine, concluded that the ingestion of fenfluramine and phentermine in combination increased the incidence of valvular heart disease. (Stip. 1/5/99 ¶ 9, Ex. B.) On September 15, 1997, AHP removed both Pondimin and Redux from the market pursuant to a request by the FDA. (Stip. 1/5/99 ¶¶ 6, 7.)

B. *MDL No. 1203 and the Diet Drug Litigation*

***2** After Pondimin and Redux were withdrawn from the market, thousands of civil actions were filed in federal and state courts nationwide on behalf of Diet Drug users. The claims in individual Diet Drug Litigation actions vary, but they principally allege state law claims including product liability, negligence, misrepresentation and breach of warranty. Some of the cases request punitive damages. The plaintiffs in these actions allege that their ingestion of the Diet Drugs caused various illnesses, including, but not limited to PPH and valvular heart disease. In addition, many actions brought by plaintiffs without present injury request legal or equitable relief in the form of medical monitoring or refunds of purchase prices.

On December 12, 1997, this court received an order from the Judicial Panel on Multidistrict Litigation transferring a number of federal Diet Drug civil actions from other districts to the Eastern District of Pennsylvania for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Since that time, the court has received over one thousand actions as part of MDL No. 1203. There are over seventeen pending motions for class certification in MDL No. 1203 actions, not including the instant motion.

In order to facilitate the administration of MDL No. 1203, the court has appointed a number of attorneys to serve on the Plaintiffs' Management Committee (the "PMC"). Pretrial Order No. 6. The defendants in the Diet Drug cases, including AHP, Interneuron Pharmaceuticals, Inc., Les Laboratories Servier, over two dozen phentermine manufacturers and distributors, health care providers, weight-loss centers, pharmacies and intermediaries, are represented by individual counsel and selected liaison counsel. The court has also appointed a Special Discovery Master to assist the court in facilitating discovery matters. Pretrial Order No. 36. The parties, the Special Master and the court continue to work toward completion of case-specific and MDL-wide discovery and to resolve related pretrial issues to facilitate the timely remand of individual civil actions to their respective transferor courts. *See Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach,* 523 U.S. 26, 40, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998) (holding cases not disposed of during MDL process must be remanded to transferor courts at or before conclusion of pretrial proceedings). Presently, there are two blocks of cases involving plaintiffs that have a serious, diagnosed medical condition which have been designated for priority in the suggestion of remand process. The first group is scheduled for suggestion of remand on September 1, 1999 and the second group is scheduled for October 1, 1999. The PMC has completed the majority of its MDL- wide expert discovery. Individual plaintiffs have not yet completed case- specific causation expert discovery and defendants have not yet completed their expert discovery, although this discovery is on schedule in accordance with various pre-trial orders and is expected to be completed by the fall of this year.

***3** In addition to the federal cases, the court is aware of many civil actions presently in state courts throughout the nation. Some states, including Pennsylvania, New York, New Jersey and California, have consolidated the Diet Drug Litigation in their respective state courts, through processes similar to MDL No. 1203. The court is aware of only a limited number of state civil actions which have proceeded to trial as of this date and is aware of only one case in which a jury verdict has been returned. The court is also aware of six states which have certified some form of medical monitoring class action. Those states include, in chronological order of certification, Texas, Washington, Illinois, New Jersey, West Virginia and Pennsylvania. [FN3]

FN3. *Earthman v. American Home Prods. Corp.,* No. 97-10-03790-CV, slip op. at 2 (Tex.Dist.Ct. Oct. 14, 1998); *St. John v. American Home Prods. Corp.,* No. 97-2-06368-4, slip op. at 4-5 (Wash.Super.Ct. Dec. 4, 1998); *Rhyne v.*

American Home Prods. Corp., No. 98-CH-04099, slip op. at 1 (Ill.Cir.Ct. Jan. 26, 1999); *Vadino v. American Home Prods. Corp.*, No. MID-L-425-98, slip op. at 31 (N.J.Super.Ct. Jan. 26, 1999); *Burch v. American Home Prods. Corp.*, No. 97-C-204[1-11], slip op. at 35-38 (W.Va.Cir.Ct. Feb. 11, 1999); *In re Pa. Diet Drugs Litig.*, Master Docket No. 9709-3162, slip op. at 39 (Pa.Super.Ct. Mar. 12, 1999).

C. *Procedural History of the Jeffers Civil Action*

The court will now set forth the basic background of the *Jeffers* civil action. On September 14, 1998, Plaintiffs filed their original class action Complaint, naming only AHP as a defendant. Plaintiffs allege that they ingested Pondimin and Redux. (Compl. ¶ ¶ 4 & 5.) [FN4] They both allege that, due to such ingestion, they are "at risk for developing valvular heart disease, cardiopulmonary dysfunction and/or primary pulmonary hypertension." *Id.* In their original Complaint, Plaintiffs seek to represent a "nationwide class of persons who were prescribed and who have taken the drugs Redux and/or Pondimin which were manufactured, marketed, sold, distributed and/or placed in interstate commerce by defendant and who either lack health coverage or who have been denied health coverage for medical monitoring and medical diagnostic procedures and testing that are necessary and appropriate." (Compl. ¶ 42.) Plaintiffs allege claims under theories of: (a) strict product liability (failure to warn); (b) strict product liability; (c) negligence; and (d) breach of implied warranty. They request injunctive relief in the form of a "court approved medical monitoring program" which would include "echocardiograms, electrocardiograms, chest x-rays and perfusion lung scans." *Id.* at 78.

FN4. In the Complaint, Plaintiffs allege that they both ingested "dexfenfluramine, and/or fenfluramine." *Id.* In her deposition, Day stated that she ingested Pondimin, but never ingested Redux. (AHP Mot. Opp. Ex. LL-18.) Jeffers stated in her deposition that she ingested a combination of Pondimin and phentermine and then ingested Redux for a short period. (AHP Mot. Opp. Ex. LL-18.)

***4** On October 27, 1998, AHP filed its Answer. On November 6, 1998, AHP filed a Third-Party Complaint against a number of phentermine manufacturers and distributors ("Phentermine Defendants"). [FN5] Subsequently, Plaintiffs and a number of Phentermine Defendants filed motions to dismiss or sever the Third- Party Complaint. On February 10, 1999, the court stayed AHP's Third-Party Complaint pending the resolution of the motion for class certification. Pretrial Order No. 461. On March 3, 1999, AHP filed its opposition to Plaintiffs' Motion for Class Certification. On March 15, 1999, Plaintiffs filed their Motion for Medical Monitoring Class Certification under Federal Rule of Civil Procedure 23(b)(2). On March 17, 1999 the court held a hearing on class certification issues.

FN5. These Third-Party Defendants include Camall Company, which is presently in Chapter 11 Bankruptcy, Century Pharmaceuticals, Duramed Pharmaceuticals, Eon Laboratories Manufacturers, Fisons Corporation, Gate Pharmaceuticals, Geneva Pharmaceuticals, H.L. Moore Drug, Ion Laboratories, Incorporated, Jones Medical Industries, King Pharmaceuticals, Harvard Drug Group, Medeva Pharmaceuticals, Parmed Pharmaceuticals, Pennwalt Corporation, Qualitest Products, Rd-Rx Pharmaceuticals, Rexar Pharmacal Corporation, Richwood Pharmaceuticals, Shire Richwood, Incorporated, Roberts Pharmaceuticals, Rosemont Pharmaceuticals, Rugby Laboratories, Seatrace, Incorporated, Smithkline Beecham, United Research Laboratories and Zenith Goldline Incorporated.

On June 24, 1999, Plaintiffs filed a Motion to Amend the Complaint together with a second motion for class certification. The Motion to Amend seeks to modify the original Complaint in a number of ways. First, the proposed Amended Complaint would limit the proposed class to those persons who have taken Pondimin or Redux "for at least thirty cumulative days during the period between May 1, 1992 and September 15, 1997 and

who have not filed a claim for personal injuries." (Pls.' Mot. Am. Compl., Ex. A ¶ 1.) Second, it would include in the class those persons with health insurance as well as those without. *Id.* Third, it specifies in greater detail the equitable relief sought, including:

> (a) creating a medical "registry" for class members in which relevant demographic, medical and scientific information concerning class members is recorded; (b) performing state-of-the-art echocardiograms for each class member; (c) performing full cardiopulmonary examinations including a chest x- ray and electrocardiogram for each class member; (d) gathering and analyzing relevant medical demographic information from class members including but not limited to the results of echocardiograms and cardiopulmonary examinations performed on class members; (e) conducting medical research concerning the incidence, prevalence, natural course and history, diagnosis and treatment of diet drug induced valvular heart disease; and (f) publishing and otherwise disseminating such information to members of the class and their physicians.

***5** *Id.* at ¶ 49. On July 12, 1999, AHP filed its opposition to the Motion to Amend the Complaint and for Class Certification.

II. *DISCUSSION*

First, the court will discuss whether the court has jurisdiction. Second, the court will analyze Plaintiffs' claims under Federal Rule of Civil Procedure 23(b)(2). Third, the court will define the scope of the class it will conditionally certify.

A. *Jurisdiction*

This court has subject matter jurisdiction over these proceedings pursuant to 28 U.S.C. § 1332. [FN6] Diversity of citizenship is present between the named class representative and the defendant. *In re School Asbestos Litig.,* 921 F.2d 1310, 1317 (3d Cir.1990) (requiring complete diversity between named class representatives and defendants to support diversity jurisdiction). Jeffers is a citizen of the state of Pennsylvania and Day is a citizen of the state of Kentucky. (Compl. ¶¶ 4 & 5.) AHP is a Delaware corporation whose principal place of business is located in Madison, New Jersey. (Stip. 1/5/99 ¶ 4.) Thus, the court finds that the parties are citizens of different states.

> FN6. That statute states: "[t]he district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between ... citizens of different States." 28 U.S.C. § 1332(a)(1).

The $75,000 jurisdictional amount is also met in this action. When a claim primarily seeks equitable or injunctive relief, "it is well established that the amount in controversy is measured by the object of the litigation." *Hunt v. Washington State Apple Adver. Comm'n.,* 432 U.S. 333, 347, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1977). In addition, the "longstanding rule in [the United States Court of Appeals for the Third Circuit] is that, for purposes of determining the amount in controversy, the value of the equitable relief must be determined from the viewpoint of the plaintiff rather than the defendant." *Pierson v. Source Perrier, S.A.,* 848 F.Supp. 1186, 1188 (E.D.Pa.1994). Also, in a diversity based class action, "[i]t is well settled that ... members of the class may not aggregate their claims in order to reach the requisite amount in controversy." *Packard v. Provident Nat'l Bank,* 994 F.2d 1039, 1044-45 (3d Cir.1993) (citing *Snyder v. Harris,* 394 U.S. 332, 89 S.Ct. 1053, 22 L.Ed.2d 319 (1969)).

***6** Here, Plaintiffs seek a comprehensive medical monitoring program that:

> a. Notifies individuals who use or used Redux and/or Pondimin of the potential harm from Redux and/or Pondimin;
> b. Aides them in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Redux and Pondimin;
> c. Provides for state-of-the-art echocardiograms for all members of the class;
> d. Provides for [complete] cardiopulmonary examinations including a chest x- ray and electrocardiogram for all members of the class;
> e. Provides for accumulation and analysis of relevant medical and demographic information from class members including, but not limited to the results of echocardiograms performed on class members;
> f. Provides for the creation, maintenance, and operation of a "registry" in which relevant demographic and medical information concerning all class members is gathered, maintained, and analyzed;

> g. Provides for medical research concerning the incidence, prevalence, natural course and history, diagnosis and treatment of diet drug induced valvular heart disease; and
> f.[sic] Publishes and otherwise disseminates all such information to members of the class and their physicians.

(Pls.' Mot. Am. Compl., Ex. A ¶ 82.) Such request for relief in this action is equitable in nature. *See Barnes v. American Tobacco Co.,* 161 F.3d 127, 132 (3d Cir.1998) (stating that plaintiffs seeking establishment of court- supervised program through which class members would undergo periodic medical examinations in order to promote early detection of diseases caused by smoking was "paradigmatic request for injunctive relief"), *cert. denied,* 526 U.S. 1114, 119 S.Ct. 1760, 143 L.Ed.2d 791 (1999); *Katz v. Warner-Lambert Co.,* 9 F.Supp.2d 363, 364 (S.D.N.Y.1998) (stating that "a claim for a medical monitoring and research fund is injunctive in nature"); *Gibbs v. E.I. DuPont de Nemours & Co.,* 876 F.Supp. 475, 479 (W.D.N.Y.1995) (stating that relief in form of common, court-supervised fund which would provide medical monitoring was injunctive in nature). [FN7]

> FN7. Plaintiffs' request for medical monitoring is truly equitable in nature and, thus, differs from those situations in which courts reject attempts to turn "what is essentially a legal claim into an equitable one merely by demanding an injunction requiring the payment of money." *Packard,* 994 F.2d at 1050 (citations omitted). *Packard* was a class action involving "sweep fees" charged to bank trust accounts. Sweep fees are charged by banks for the service of looking daily for idle cash and investing it in interest-bearing vehicles until the cash is either invested long-term or distributed to the beneficiary. *Id.* at 1043. In *Packard,* the Third Circuit held that the plaintiffs could not meet the jurisdictional amount. The Third Circuit stated: "[h]ere, virtually all the relief sought is remediable by money damages. The only truly equitable relief sought in this case is an order requiring [the defendant] to provide adequate notice of its sweep fees to trust beneficiaries and to tie future sweep fees to the cost of providing the service." *Id.* at 1050. Thus, the relief requested in *Packard* is distinguishable from the claim for relief in *Jeffers* which includes ongoing medical studies.

***7** In addition, the value of the litigation to each class member in obtaining the benefits of diagnostic testing and medical research is reasonably likely to exceed $75,000. In *Katz,* the court held that class action claims for a medical monitoring and research fund met the jurisdictional amount. *Katz,* 9 F.Supp.2d at 364. *Katz* involved litigation over the health risks associated with Rezulin, a drug used for treating diabetes. *Id.* The court found that the class request for a medical monitoring and research fund was injunctive in nature. *Id.* Next, the court proceeded to determine the value of the object of the litigation from the plaintiffs' viewpoint. *Id.* In holding that the class's request for medical research satisfied the jurisdictional amount, the court stated:

> But what is the value to an individual user of Rezulin of the medical monitoring and research fund that is the object of this litigation? In one sense, it is speculative, because no one knows how much ultimate benefit any given Rezulin user will derive from such a fund. But in another sense it is appropriately measurable as the cost to defendant of creating such a fund, or at least the research portion of it, for without such research expenditure, no plaintiff would be likely to receive any research benefit. Put another way, in order to receive the putative benefits of the contemplated medical research, a plaintiff would either have to fund the research herself or to prevail in this lawsuit.
> This reasoning is applicable not only to the individually named plaintiff ... but also to each member of the rest of putative class. Whatever may be the case as to the proposed monitoring, as to the research component of the proposed relief there is no question of dividing the cost by the number of plaintiffs in the putative class to determine the value to each plaintiff, because ... the full amount of the research, rather than some fraction of it, must be funded to benefit any single member of the contemplated class. Indeed, plaintiff demands that the full amount of research be undertaken regardless of the number of members of the class because each and every member is entitled ... to the protection against Rezulin's hazards that only fully funded future

research can hope to achieve.
Id. at 364-65. Here, Plaintiffs request similar medical monitoring relief, including a research fund. The court agrees with and adopts the reasoning in *Katz* and finds that it has subject matter jurisdiction over this civil action pursuant to 28 U.S.C. § 1332.

B. *Class Action Certification*

***8** To qualify for class treatment, an action must satisfy the requirements of Federal Rule of Civil Procedure 23(a) and must fit into one of the three subsections of Rule 23(b). *Barnes,* 161 F.3d at 140. The court will review Plaintiffs' claims under Rule 23(a) and (b) in order.

1. Requirements of Federal Rule of Civil Procedure 23(a)

Under Rule 23(a) the court must find that:

> (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed.R.Civ.P. 23(a). Thus, Rule 23(a) requires numerousity, commonality, typicality and adequacy of representation.

The first two conditions, numerousity and commonality, are clearly satisfied in the *Jeffers* action. Rule 23(a)(1) requires that the class be "so numerous that joinder of all members is impracticable." Fed.R.Civ.P. 23(a)(1). As discussed above, millions of prescriptions for Redux and Pondimin were written. Joinder of hundreds of thousands, if not millions, of claimants would certainly qualify as impracticable. Under Rule 23(a)(2), there must be "questions of law or fact common to the class." Fed.R.Civ.P. 23(a)(2); *see Lake v. First Nationwide Bank,* 156 F.R.D. 615, 624 (E.D.Pa.1994) (noting that "a single common question is sufficient to satisfy Rule 23(a)(2)"). There are a number of common issues among class members, including the chemical composition and biological effects of Pondimin and Redux, the labeling and warnings included with the drugs and AHP's knowledge of the alleged side effects. Thus, the court finds the requirements of numerousity and commonality are satisfied.

Rule 23(a) also requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed.R.Civ.P. 23(a)(3); *see Barnes,* 161 F.3d at 141 (stating that "typicality requirement is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals"). The class members have a strong common interest in establishing the fund at issue. Both of the named class representatives and the class as a whole will benefit from the relief requested here. The class members allege that they all ingested Pondimin or Redux and that those drugs increased their risk of contracting PPH or valvular injury. They request medical monitoring in the form of diagnostic testing and the collection and research of medical data for all members. Thus, it can be said that the class representatives' interests are aligned with those of the entire class and that the representatives will work to benefit the entire class.

***9** Lastly, Rule 23(a) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed.R.Civ.P. 23(a)(4). This requirement has two components, one which requires an inquiry into whether class counsel is qualified and will advance the interests of the entire class and a second which asks whether the named class representatives' interests are "sufficiently aligned with those of the absentees". *Georgine v. Amchem Prods., Inc.,* 83 F.3d 610, 630 (3d Cir.1996), *aff'd sub nom., Amchem Products, Inc. v. Windsor,* 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997); *see also Barnes,* 161 F.3d at 141 (stating Rule 23(a)(4) "serves to uncover conflicts of interest between named parties and the class they seek to represent"). The class counsel in this action are also members of the PMC. *See* Pretrial Order No. 6. These attorneys are both experienced and qualified in handling mass tort cases such as this. The court finds that class counsel is both able and competent to represent the class. Additionally, the named representatives' interests are sufficiently aligned with those of the class members such that there is no conflict of interest between them. As discussed, the class representatives have a strong individual interest in obtaining the requested diagnostic testing and that interest is sufficiently aligned with the common interests of the absentee class members. Moreover, the class as a whole has a strong common interest in the collection of medical data and research into the

cause and treatment of the illnesses alleged to be caused by the ingestion of fenfluramine and dexfenfluramine. The court finds no conflict of interest which would render Plaintiffs inadequate representatives of the class. To the extent that AHP asserts that there are differences between the factual and legal claims of the class members, the court will address such differences under its Rule 23(b)(2) analysis below. The court finds that the Rule 23(a) requirements of numerousity, commonality, typicality and adequacy of representation are satisfied in this case.

2. Federal Rule of Civil Procedure 23(b)(2)

Rule 23(b)(2) requires that "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed.R.Civ.P. 23(b)(2). Thus, there are two elements implicit in Rule 23(b)(2), first that the defendant is alleged to have acted in some uniform way toward the class that would make relief appropriate and, second, that the injunctive relief requested is applicable to the entire class. Unlike the requirements of Rule 23(b)(3), there is no "superiority" or "predominance" requirement for Rule 23(b)(2) classes. *Compare* Fed.R.Civ.P. 23(b)(2), *with* Fed.R.Civ.P. 23(b)(3) (requiring "that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy"). However, because a 23(b)(2) class is dependent on the uniformity of both the defendant's actions toward the class and the injunctive relief applicable to the class, an analysis of whether individual issues exist among class members which would destroy the "cohesive nature" of the class claims is required. In *Barnes,* the Third Circuit stated the reasoning for requiring such cohesion:

> ***10** Because of the cohesive nature of the class, Rule 23(c)(3) contemplates that all members of the class will be bound. Any resultant unfairness to the members of the class was thought to be outweighed by the purposes behind class actions: eliminating the possibility of repetitious litigation and providing small claimants with a means of obtaining redress for claims too small to justify individual litigation.

Barnes, 161 F.3d at 143 (quoting *Wetzel v. Liberty Mut. Ins. Co.,* 508 F.2d 239, 248-49 (3d Cir.1975)). Furthermore, the non-opt out nature of a Rule 23(b)(2) class further requires that there be cohesiveness of the class members' claims. *Id.* at 142 (stating that "a (b)(2) class may require more cohesiveness than a (b)(3) class"). Thus, the court must determine whether the class claims alleged in *Jeffers* are cohesive.

Plaintiffs assert that the claims in this action are cohesive. They note that several published studies have linked the use of fenfluramine and dexfenfluramine to unusually high incidences of PPH and heart valve injury and they proffer expert discovery to support this conclusion. (Pls.' Proposed Findings of Fact App. I, Decl. of John Farquhar, M.D. at 9.) (concluding that "it appears that significant heart valve damage emerges even with a relatively brief exposure to these drugs" and that "the possibility that even minor valve damage may progress over time after cessation of diet drug use has not been excluded"); (Pls.' Proposed Findings of Fact App. IV. A, Expert Report of John Farquhar, M.D. at 2.) (stating that "[b]rief exposures of one month or more are probably sufficient to cause harm"). Thus, Plaintiffs assert that the proposed class members have all been placed at an increased risk of contracting PPH and heart valve damage. They also set forth expert discovery which supports their assertion that the relief requested applies to the class as a whole. (Pls.' Proposed Findings of Fact App. I, Decl. of Dean Karalis, M.D. at 7.) (stating that "based on the recommendations of the [Department of Health and Human Services, the American College of Cardiology and the American Heart Association,] the standard of care for evaluating patients exposed to Dexfenfluramine and Fenfluramine includes a thorough history and physical exam" and that "echocardiography should be performed in all patients exposed to these diet drugs"). They further assert that AHP is liable to the entire class under theories of strict product liability, negligence and breach of implied warranty. Specifically, Plaintiffs allege that AHP had knowledge of these side effects prior to the withdrawal of the drugs and failed to warn the proposed class of those dangers or take other appropriate action. (Pls.' Proposed Findings of Fact App. IV. F, Decl. James Oury, M.D. at 11.) (concluding that AHP failed to conduct appropriate review of clinical data concerning persons ingesting fenfluramine and dexfenfluramine and that labeling failed to contain warnings regarding PPH and heart

valve injury at appropriate times). Based on Plaintiffs' allegations that AHP acted in such a way as to create liability to the class as a whole and that injunctive relief is applicable to the class as a whole, the court finds that the class claims are cohesive.

***11** However, AHP asserts that the claims are incapable of Rule 23(b)(2) class treatment. First, AHP asserts that there are factual issues that differ from class member to class member that destroy cohesiveness. Second, AHP argues that the state law applicable to each class member varies to such a degree that class treatment is inappropriate. The court will address these issues and will also address a third issue, which is that a number of state courts have already certified medical monitoring classes applicable to residents of their states.

a. Individual Factual Issues

As noted above, Rule 23(b)(2) contains two components, one which requires the defendant to have acted in some uniform way toward the class so as to require relief and a second which requires the class be entitled to the same relief. AHP argues that there are a number of factual issues which vary from class member to class member. AHP believes that these individual issues make class treatment inappropriate under Rule 23(b)(2).

The primary individual issues AHP raises include: (1) differences in the class members' duration of, amounts of and combinations of the drugs ingested; (2) AHP's varying knowledge of alleged side effects and the changing contents of warning labels over the times of ingestion; (3) differences in the prescribing physicians' knowledge, conditions and warnings under which the drugs were prescribed; (4) differences in class members' actual need for the form of monitoring requested; (5) differences among class members involving pre- existing injuries or non-Diet Drug related conditions that already require the monitoring requested; and (6) differences in affirmative defenses available to AHP against individual class members. (AHP Mem. Opp. at 68.) AHP believes that these issues will present grounds for it to challenge, on an individual basis, either liability or the need for the equitable relief requested and that class treatment would prevent AHP from having the opportunity to make such challenges.

The court agrees with AHP's assertion that these individual issues may present some difficulty in treating the claims in a single class, particularly as to the affirmative defenses AHP may seek to assert. However, the court is presently of the view that these difficulties are not insurmountable and could be dealt with through either the development of subclasses or through exclusions to the class. For example, the issue of the duration of ingestion has already been corrected for in the proposed Amended Complaint in that persons who ingested the drugs for less than thirty cumulative days will be excluded from the class. (Pls.' Mot. Am. Compl., Ex. A ¶ 1.) This comports with the Plaintiffs' position, supported by expert discovery, that exposure to the drugs for one month or more may cause harm and that anyone ingesting the drugs for that period of time is at an increased risk of contracting PPH or valvular damage. (Pls.' Proposed Findings of Fact App. IV. A, Expert Report of John Farquhar, M.D. at 2.)

***12** Also, AHP alleges that some of the proposed class members have ingested phentermine in combination with Pondimin or Redux, while others have not. (AHP's Mem. Opp. at 47.) If AHP can demonstrate through expert evidence that the use of phentermine in combination with Pondimin or Redux alters the liability analysis or the applicable relief to the class, a subclass mechanism could be utilized to address those factual differences between class members.

In addition, AHP asserts that the directions for Pondimin stated that the drug should only be taken for a few weeks. *Id.* at 49. Presumably, AHP could attempt to raise a defense of misuse or contributory negligence against those persons who ingested the drug for longer periods of time. As the litigation develops, should this issue warrant it, the class could be divided into subclasses based upon the particular drug ingested and the duration of such ingestion. Such a subclass would allow AHP to assert such a defense against those persons ingesting Pondimin.

AHP also asserts that the warning labels on Pondimin varied as to PPH over time, creating individual issues of when the drug was prescribed and ingested. *Id.* at 51-52. Again, if necessary, subclasses based on these differences would be appropriate to preserve this defense.

AHP claims that some class members may have non-Diet Drug related reasons for the diagnostic monitoring requested and, thus, should not be granted that relief. *Id.* at 55. If it appears that this issue does become one which AHP will assert, AHP's position could be preserved by excluding those persons from the diagnostic portion of the overall equitable relief requested.

In sum, the factual issues that AHP raises should be further explored and, to the extent that they alter the liability analysis or the applicable relief to the class, subclasses or exclusions should be applied accordingly. Because many of the issues would apply across potential subclasses, it cannot be said that each individual issue will spawn its own distinct subclass. The court finds that, at this time, these individual issues do not present insurmountable difficulties which would destroy cohesion.

Along these lines, AHP further argues that the Third Circuit's holding in *Barnes* forecloses the possibility of class treatment here. (AHP's Mem. Opp. at 43.) In *Barnes,* the Third Circuit affirmed the District Court in decertifying a medical monitoring fund of tobacco smokers. The court stated that "[w]e believe that addiction, causation, the defenses of comparative and contributory negligence, the need for medical monitoring and the statute of limitations present too many individual issues to permit certification." *Barnes,* 161 F.3d at 143. However, a comparison with the class at hand and that in the *Barnes* tobacco litigation reveals some significant differences. *Barnes* involved numerous defendants who, in turn, manufactured hundreds of brands of cigarettes, many of which contained different ingredients at different times. *Id.* at 135. Plaintiffs asserted that the levels of nicotine and other "toxic substances" were altered to induce addiction, which they claimed caused their exposure to the tobacco products. *Id.* at 144-45. Thus, nicotine addiction and levels of nicotine in cigarettes constituted individual issues which destroyed cohesion in the class. In the Diet Drug Litigation, there are only two related chemical compounds, fenfluramine and dexfenfluramine, which were sold as only two brands, Pondimin and Redux, which Plaintiffs allege cause the illnesses for which they request monitoring. Plaintiffs do not allege that the chemical compounds of these pharmaceutical products were altered in any way during the course of the products' market lives. Also, there are no claims of addiction in the *Jeffers* action as there were in *Barnes.* The court finds that the claims of the proposed *Jeffers* class are far more cohesive claims than those found in *Barnes.*

***13** Furthermore, the individual issues which AHP raises, including duration of use and combination of drugs, are more susceptible to subclass treatment than the claims relating to tobacco use or, to take another example of recent mass tort class litigation, claims stemming from asbestos exposure. In those cases, exposure is often difficult to quantify and confirm as the exposure levels could vary greatly from claimant to claimant and, in many cases, exposure extended over decades. In the case of asbestos, there are several possible forms of exposure with varying degrees of danger and, notably, there could be persons who are not aware if they have been exposed. Conversely, the class members' ingestion of the Diet Drugs is discrete and ascertainable. The dates, duration and amounts of ingestion and the combination of drugs ingested can be confirmed through the use of fact sheets and medical records. If individual issues in the Diet Drug Litigation arise and subclasses are created, the members of those subclasses which do not qualify for the monitoring requested will be readily identifiable from the registration forms and the supporting documentation which will be required. The court finds that the proposed class here is more cohesive than those which would generally be found in tobacco or asbestos cases.

If and when AHP asserts its challenges or affirmative defenses to liability based on the individual issues discussed above, the court will evaluate them. If the issues alter the liability analysis or the applicable relief to the class, the court could utilize subclass mechanisms to allow the defenses to be properly raised at trial. However, at this point, evaluating the merits of the defenses AHP claims it could make is premature. For instance, in its Answer, AHP raises thirty-nine affirmative defenses to the *Jeffers* Complaint. (Answer at 14-22.) Experience has demonstrated that defendants do not raise every affirmative defense asserted in their Answer at trial. It is unlikely that AHP will raise every one of these defenses at trial, just as it is unlikely that every conceivable factual distinction between the class members will alter the liability analysis or the appropriate relief. Many of these defenses could be asserted against the class as a whole and cohesion

would not be diminished.

If the individual issues, as a whole, destroy cohesion or deprive the parties of their constitutional right to due process, then the court will exclude parts of the class or decertify the class in its entirety accordingly. However, it would be premature for the court at this point to delve into the merits of AHP's potential defenses to liability and the applicability of the equitable relief on these sorts of issues before they are fully raised and challenged. For instance, the court expects that AHP will not raise those defenses which are unsupported by the still developing expert evidence. Also, Plaintiffs may move to strike any of the defenses which are raised. Many of the above issues necessarily involve competing expert evidence regarding both the alleged side effects of Pondimin and Redux, as well as the diagnostic techniques to evaluate whether those side effects are present in individual class members and the scope and necessity of ongoing medical monitoring. The court will hear and evaluate such evidence when the parties set forth a briefing and hearing schedule as is contemplated in the accompanying Order. At present time, the court finds that Plaintiffs' claims are sufficiently cohesive to warrant conditional certification.

b. Variance of State Law

***14** AHP points out that not all states have explicitly recognized an asymptomatic plaintiff's claim for medical monitoring and that those states which recognize such a cause of action have varying legal elements. (AHP's Mem. Opp. at 84 & 88.) AHP also argues that some states have rejected asymptomatic plaintiffs' claims under medical monitoring theories. *Id.* at 89-90. AHP argues that the variance of state law makes the class claims unmanageable. Plaintiffs asserts that the law of Pennsylvania should be applied to the class as a whole because Pennsylvania has the greatest interest in applying its law to the claims at issue.

First, the Rules Enabling Act presents an obstacle to Plaintiff's proposed method of adjudicating these claims. The Rules Enabling Act states that the Federal Rules of Civil Procedure "shall not abridge, enlarge or modify any substantive right." 28 U.S.C. § 2072(b); *see also Ortiz v. Fibreboard Corp.*, 527 U.S. 815, ----, 119 S.Ct. 2295, 2314, 144 L.Ed.2d 715, ---- (1999) (citing *Guaranty Trust Co. v. York*, 326 U.S. 99, 105, 65 S.Ct. 1464, 89 L.Ed. 2079 (1945), for proposition that " '[i]n giving federal courts 'cognizance' of equity suits in cases of diversity jurisdiction, Congress never gave, nor did the federal courts ever claim, the power to deny substantive rights created by State law or to create substantive rights denied by State law' "). Essentially, Plaintiffs request that Federal Rule of Civil Procedure 23 act as the conduit through which Pennsylvania's medical monitoring cause of action extend to all class members, regardless of whether a given class member's claim arises in a jurisdiction which does not recognize such a legal theory absent injury. Such an action would violate the Rules Enabling Act.

Furthermore, Plaintiffs' view contradicts the choice of law principles in Pennsylvania. [FN8] Pennsylvania choice of law rules require a determination of whether there is a false conflict in the law of the states at issue. *LeJeune,* 85 F.3d at 1071. Where the laws of two states are in opposition and the jurisdictions have a governmental interest in applying their respective laws, there is not a false conflict. *See id.* (stating "[a] false conflict exists where 'only one jurisdiction's governmental interests would be impaired by the application of the other jurisdiction's law.' ") (quoting *Lacey v. Cessna Aircraft Co.*, 932 F.2d 170, 187 (3d Cir.1991)). If a false conflict does not exist, the court must make a second determination of which state has the greater interest in the application of its law. *Id.*

> FN8. The Third Circuit has stated: "[i]n choosing which law applies, a federal court sitting in diversity must apply the choice-of-law rules of the forum state." *LeJeune v. Bliss-Salem, Inc.*, 85 F.3d 1069, 1071 (3d Cir.1996). As this action originated in the United States District Court for the Eastern District of Pennsylvania, Pennsylvania's choice of law rules apply.

***15** Those states which recognize a medical monitoring claim have a governmental interest in protecting its citizens from exposure to toxic substances. *See, e.g., Redland Soccer Club, Inc. v. Department of the Army and Dep't of Defense of the U.S.*, 548 Pa. 178, 696 A.2d 137, 145 (Pa.1997) (setting forth "several important reasons to

recognize claims for medical monitoring"). Conversely, those states which do not recognize a claim for medical monitoring also have a governmental interest for doing so, whether it be to encourage the development of new pharmaceutical products or to avoid the burden of increased litigation state courts would face in abandoning the traditional tort requirement that plaintiffs demonstrate a physical injury. For example, on July 9, 1999 the Louisiana Legislature enacted a modification to the Louisiana civil code regarding tort damages, to prevent asymptomatic plaintiffs from recovering for medical monitoring claims. 1999 La. Sess. Law Serv. 989 (West) (modifying statute to include language that "[d]amages do not include costs for future medical treatment, services, surveillance, or procedures of any kind unless such treatment, services, surveillance, or procedures are directly related to a manifest physical or mental injury or disease") (amending La. Civ.Code Ann. art. 2315 (West 1999)). In doing so, the Legislature explicitly overruled the Louisiana Supreme Court's holding in *Bourgeois v. A.P. Green Indus.*, 716 So.2d 355, 361 (La.1998). Thus, the court finds that no false conflict exists, at least in those jurisdictions that do not recognize medical monitoring claims absent injury or in those with medical monitoring claim elements significantly different than Pennsylvania's.

Next, the court must determine whether Pennsylvania has a greater interest in the application of its law over the interests of the states in which class members were prescribed and ingested the Diet Drugs. The ingestion and prescription of these Diet Drugs occurred on a nationwide basis. Most of the proposed class members have no ties whatsoever with Pennsylvania. Although AHP's subsidiary, Wyeth-Ayerst Laboratories Division, has its principal offices in St. David's Pennsylvania and many of AHP's activities regarding the drugs at issue occurred in Pennsylvania, AHP conducted its FDA contacts and various marketing efforts in other jurisdictions as well. In light of all the circumstances, the court finds that the jurisdictions in which each class member was prescribed and ingested the Diet Drugs have a strong interest in applying their applicable law to the sale, prescription and ingestion of pharmaceuticals within its borders, which is the conduct which gave rise to the class members' claims. *See LeJeune,* 85 F.3d at 1072 (stating that "[w]here the site of an accident is not fortuitous, the place of injury assumes much greater importance, and in some instances may be determinative") (quotation omitted); *see also Petrokehagias v. Sky Climber, Inc.*, No. 96-6965, 1998 WL 227236, at *7 (E.D.Pa. May 4, 1998) (holding in product liability suit that Massachusetts law applies where plaintiffs were residents of Pennsylvania and New Jersey and product at issue was leased from defendant situated in New Jersey, but plaintiffs' injuries occurred in Massachusetts). Thus, the court will apply the law of the state in which each class member's claim arose rather than apply Pennsylvania substantive law to all class members.

***16** In addition to requiring a review of the state law regarding medical monitoring, the court will also need to analyze the law of any underlying cause of action, for example negligence or strict liability, which is required under the applicable state law to succeed on a claim for medical monitoring. *See, e.g., Redland Soccer Club, Inc. v. Department of the Army and Dept. of Defense of the U.S.*, 548 Pa. 178, 696 A.2d 137, 145 (Pa.1997) (requiring that exposure to toxic substances be "caused by the defendant's negligence" as element of medical monitoring); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993) (requiring that "exposure was caused by the defendant's negligence"); *Potter v. Firestone Tire & Rubber Co.*, 6 Cal.4th 965, 25 Cal.Rptr.2d 550, 863 P.2d 795, 822 (Cal.1993) (requiring that "liability [be] established under traditional tort theories of recovery").

The court finds that the application of the laws of the states does not necessarily render class treatment unmanageable. Nor does it destroy cohesion of the class claims. Rather, it requires the establishment of subclasses dependent on whether the elements of medical monitoring or the underlying legal action significantly differ. While some states recognize a claim for medical monitoring absent injury, other states require some injury for a tort claim to proceed. *See, e.g., Wood v. Wyeth-Ayerst Labs.*, No. 97-CI-5873, slip op. at 2-4 (Ky. Cir. Ct. June 17, 1999) (granting AHP's motion for judgment on pleadings in class action for medical monitoring in state Diet Drug Litigation because "cause of action cannot be maintained, absent an allegation of physical injury or harm"); 1999 La. Sess. Law Serv. 989 (West) (requiring that claim for medical monitoring be "directly related to

a manifest physical or mental injury or disease"). The class which the Plaintiffs seek to certify is not comprised only of persons who ingested Pondimin or Redux who have no present injury. Rather, Plaintiffs bring this litigation on behalf of those persons "who have not filed a claim for personal injuries." (Pls.' Mot. Am. Compl., Ex. A ¶ 1.) Thus, some persons in the class may have some injury which is unknown at present time, which is precisely why they request diagnostic testing. Others may have some known injury but have simply not filed suit, whether it be because their injuries were minor and not likely to be worth the expense of individual litigation or for other reasons. If those with known injury demonstrate that monitoring relief is appropriate, such as to determine if their condition worsens, then subclass treatment may be appropriate. Such a subclass would permit recovery for medical monitoring in those states requiring some injury, such as Louisiana and Kentucky. [FN9] *See, e.g., In re Telectronics Pacing Sys., Inc.,* 172 F.R.D. 271, 287 (S.D.Ohio 1997) (stating in Rule 23(b)(3) class action that "[i]n some states, medical monitoring is only recoverable if the plaintiff shows physical injury" and dividing the class into subclasses based on state law accordingly). Thus, the conditional class will include a subclass of persons with known injury who have not filed a personal injury claim. However, class members who are asymptomatic and whose claims arise in jurisdictions that adhere to the traditional requirement of an injury for a tort action to proceed would have to be excluded from the class entirely.

> FN9. AHP also contends that Oregon and North Carolina have rejected medical monitoring for asymptomatic plaintiffs. (AHP Mem. Opp. at 89-90.) It also contends that Maryland, Mississippi and Vermont have not yet reached the issue. *Id.* at 91.

***17** Because Plaintiffs have been proceeding under the view that Pennsylvania law would apply to the entire class, they have not had opportunity to brief the issue of varying state law, nor has AHP fully addressed the issue. The court will require such briefing within thirty days from this conditional certification and will then modify the class as required. The court expects that it will create a number of subclasses based upon the variance of both medical monitoring law and variances in the underlying claims of strict liability, negligence and breach of warranty. Furthermore, to the extent that a different legal standard may apply to certain members of the class, the factfinder at trial could make alternate findings in accordance with those standards. Thus, the court finds that the variance in state law does not render the class claims non-cohesive.

c. Existing Class Actions

As noted above, a number of state courts have certified statewide medical monitoring classes in the Diet Drug Litigation. These states include Texas, Washington, Illinois, New Jersey, West Virginia and Pennsylvania. Plaintiffs request that this court certify a nationwide class action despite the fact that these state courts have already certified similar classes. (Pl.'s Reply Mem. at 5 n.7.)

The civil actions in MDL No. 1203 are before the court on diversity jurisdiction and so there is overlapping jurisdiction over the Diet Drug Litigation. Furthermore, the court has in the past and will in the future conduct MDL No. 1203 in a manner that encourages coordination between state and federal courts, rather than in a manner which results in conflicting deadlines and discovery requirements for parties. In this light, the court will exclude from the conditional class those persons who are, on the date of this Order, class members of a certified class action in a state court for medical monitoring and they shall remain excluded for as long as they are members of such class. *See, e.g.,* Manual for Complex Litigation 3d § 30.15, at 221 (1995) (stating that "to the extent a state court class action has progressed further than the federal action, the court may want to consider an appropriate definition to exclude the members of that class").

C. *Conditional Certification of Class*

Having found that the elements of Rule 23(a) are satisfied and that the medical monitoring claims are proper for class treatment under Rule 23(b)(2), the court will now undertake to define the scope of the class. The court begins with the proposition that in defining the class structure the class is subject to modifications through further inclusion, exclusion and subclass treatment of class members. *See*

Fed.R.Civ.P. 23(c)(1) (stating that an order certifying a class "under this subdivision may be conditional, and may be altered or amended before the decision on the merits"); *Barnes,* 161 F.3d at 140 (stating that "District Courts are required to reassess their class rulings as the case develops"). However, the court also notes that in certifying a class, the court should take care to certify the class as close as reasonably possible to that which satisfies Rule 23. *See, e.g.,* Manual for Complex Litigation 3d § 30.11, at 215 (1995) (stating that "[u]ndesirable consequences may follow when an expansive class, formed on insufficient information, is later decertified or redefined"). Thus, the court will define the class as close as reasonably possible to what is required by Rule 23 under its present understanding of the nature of this litigation.

***18** Plaintiffs' motion to amend the Complaint alters the scope of the proposed class in several key aspects. AHP, in its opposition memorandum, notes that the proposed amendments were made long after the deadlines established by this court regarding motions for class certifications and significantly after the issue was briefed and argued. However, the court itself is under a duty to modify any class it conditionally certifies as the case develops. *Barnes,* 161 F.3d at 140. Thus, the closer the scope of the conditionally certified class is to what the final class certified class will be, the better for the court, the parties and the class members. The court will grant Plaintiffs' motion to amend and will conditionally certify the class in accordance with the proposed amendments and the preceding discussion as they best represent the court's understanding of the case as it presently stands. Furthermore, the court will expect further briefing, in which AHP and the Plaintiffs may make such objections to the class definition as it sees fit.

With these concerns in mind, the court outlines the scope of the class as follows: first, the conditional class will consist of all persons who were prescribed and ingested either fenfluramine or dexfenfluramine for at least thirty cumulative days during the period between May 1, 1992 and September 15, 1997 and who have not filed a claim for personal injuries in a court of competent jurisdiction. Second, the conditional class will exclude persons who are, and for so long as they continue to be, class members of a certified state class action for medical monitoring. Third, the conditional class will exclude those class members who are asymptomatic and whose claims arose under the law of a state which does not recognize claims for medical monitoring absent injury.

Furthermore, the court envisions a number of subclasses which would assist the court in its management of the class and the resolution of the claims therein. The court will invite additional briefing regarding the creation of subclasses or redefinitions of the class to address the factual and legal issues which may vary within the class and a discussion of proposed representatives for such subclasses as may be appropriate. This would necessarily include a breakdown of state law regarding medical monitoring and the underlying causes of action on strict liability, negligence and breach of implied warranty as it stands in the various states in which the class members' claims arise.

D. *Summary*

The class members' claims are such that individual ligation would not result in achieving the appropriate relief for the class members. Absent class treatment, the class members will be unable to obtain the benefit of collection and research of medical data and thereby better understand issues such as latency periods and techniques of diagnosis of the diseases which the class believes are caused by the ingestion of the drugs. While Plaintiffs will ultimately have to prove that they and the class are, in fact, at a risk of contracting these diseases, the court notes that there is sufficient medical study and research at this time to warrant conditional certification. There exist individual issues which will be a challenge to the court and the parties in resolving the class claims, including individual factual issues and variance of applicable state law. Rather than turn its back on these challenges, the court will conditionally certify the class as outlined above and will continue to review the class and redefine it as necessary until it can be said with some certainty that class treatment is unacceptable under *Barnes,* Rule 23 or the parties' constitutional rights.

***19** As the accompanying Order directs, the court will expect the parties to further brief and present to the court their views on issues of developing scientific studies, potential class structures to address variance of state law and individual issues. However, the court finds that certification is

appropriate at this juncture as it has found the requirements of Rule 23(a) and (b) are met under Plaintiffs' theory that the class members are entitled to uniform, equitable relief. That theory is founded on such scientific studies and findings which would at least present a triable issue of fact for a factfinder. Thus, in the interests of granting the equitable relief requested and noting that the class itself is unable to perform those equitable tasks on an individual basis, the court certifies a conditional medical monitoring class as outlined above.

III. *CONCLUSION*

For the foregoing reasons, the court will grant the motion for class certification as discussed above.

An appropriate Order follows.

PRETRIAL ORDER NO. 865

AND NOW, TO WIT, this 26th day of August, 1999, upon consideration of plaintiffs Barbara Jeffers' and Johnna Day's Motions for Class Certification Pursuant to Federal Rule of Civil Procedure 23(b)(2) and Motion to Amend the Complaint and defendant American Home Products Corporation's responses thereto, IT IS ORDERED that:

1. the plaintiffs' Motion for Class Certification filed March 15, 1999 (Document # 200709) is DENIED AS MOOT;
2. the plaintiffs' Motion to Amend the Complaint (Document # 200940) is GRANTED;
3. the plaintiffs' Motion for Class Certification filed June 24, 1999 (Document # 200940) is GRANTED as stated in the accompanying Memorandum and below;
4. the plaintiffs shall, within ten (10) days from the date of this Order, submit to the court a proposed form of notice to the class;
5. the plaintiffs and defendant American Home Products Corporation shall, within seven (7) days from the date of this Order, submit to the court a proposed briefing schedule to resolve the outstanding issues discussed in the accompanying memorandum, with such schedule to conclude preliminary briefing within thirty (30) days from the date of this Order; and
6. the court will, upon approval of the briefing schedule, conduct a hearing on the above issues to follow shortly after the close of briefing.

IT IS FURTHER ORDERED THAT the court hereby CONDITIONALLY CERTIFIES a class under Federal Rule of Civil Procedure 23(b)(2) consisting of all persons who were prescribed and ingested either fenfluramine (marketed under the brand name Pondimin) or dexfenfluramine (marketed under the brand name Redux) for at least thirty cumulative days during the period between May 1, 1992 and September 15, 1997 and who have not filed a claim for personal injuries in a court of competent jurisdiction.

***20** IT IS FURTHER ORDERED that the above conditional class shall exclude all persons who are, and for so long as they continue to be, class members of a certified state class action for medical monitoring.

IT IS FURTHER ORDERED that the above conditional class will exclude those class members who are asymptomatic and whose claims arise under the law of a state which does not recognize claims for medical monitoring absent injury.

SO ORDERED.

1999 WL 673066 (E.D.Pa.)

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2003 WL 21518104
--- S.E.2d ----
(Cite as: 2003 WL 21518104 (W.Va.))

H

Supreme Court of Appeals of
West Virginia.

In re WEST VIRGINIA REZULIN LITIGATION
and
State of West Virginia, ex rel. Sandra McCaffery, et al., Petitioners,
v.
The Honorable John A. Hutchison, Judge of the Circuit Court of Raleigh County;
Warner-Lambert Company; and Parke-Davis, Respondents.

Nos. 30958, 30963.

Submitted Feb. 26, 2003.
Decided July 3, 2003.

Users of prescription drug brought action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market that subjected users to increased risk of liver disease and injury. The Circuit Court, Raleigh County, John A. Hutchison, J., denied users' motion to certify a class. Users appealed. The Supreme Court of Appeals, Starcher, C.J., held that: (1) class of approximately 5,000 users of drug met threshold requirements for certification of a class, and (2) common questions predominated over individual questions and class action was superior to other litigation methods for resolution of claims.

Reversed and remanded.

West Headnotes

[1] Appeal and Error ⚿949
30k949 Most Cited Cases

Supreme Court of Appeals reviews a circuit court's order granting or denying a motion for class certification under an abuse of discretion standard. Rules Civ.Proc., Rule 23.

[2] Appeal and Error ⚿893(1)
30k893(1) Most Cited Cases

An interpretation of the West Virginia Rules of Civil Procedure presents a question of law subject to a de novo review.

[3] Courts ⚿97(1)
106k97(1) Most Cited Cases

A federal case interpreting a federal counterpart to a West Virginia rule of procedure may be persuasive, but it is not binding or controlling.

[4] Parties ⚿35.33
287k35.33 Most Cited Cases

The party who seeks to establish the propriety of a class action has the burden of proving that prerequisites provided in rules of civil procedure have been satisfied. Rules Civ.Proc., Rule 23.

[5] Parties ⚿35.9
287k35.9 Most Cited Cases

Whether the requisites for a class action exist rests within the sound discretion of the trial court. Rules Civ.Proc., Rule 23.

[6] Parties ⚿35.35
287k35.35 Most Cited Cases

A circuit court should determine whether the prerequisites of a class action have been established as soon as practicable after the commencement of the action. Rules Civ.Proc., Rule 23(c)(1).

[7] Parties ⚿35.37
287k35.37 Most Cited Cases

Trial court is not authorized to conduct a preliminary inquiry into the merits of a suit in order to determine whether it may be maintained as a class action. Rules Civ.Proc., Rule 23.

[8] Parties ⚿35.37
287k35.37 Most Cited Cases

Rule governing certification of a class does not require circuit court in every case to fully certify a class before proceeding to a consideration of the merits. Rules Civ.Proc., Rule 23.

[9] Parties ⚿35.37
287k35.37 Most Cited Cases

When a circuit court is evaluating a motion for class

certification, the dispositive question is not whether plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of rule governing class actions are met. Rules Civ.Proc., Rule 23.

[10] Parties ⚿35.69
287k35.69 Most Cited Cases

Trial court was not authorized to consider the merits of parties' claims and defenses in considering motion for class certification in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market. Rules Civ.Proc., Rule 23.

[11] Parties ⚿35.5
287k35.5 Most Cited Cases

Before certifying a class, a circuit court must determine that the party seeking class certification has satisfied all four prerequisites, i.e., numerosity, commonality, typicality, and adequacy of representation, and has further satisfied one of the three subdivisions in rule governing class action; as long as these prerequisites to class certification are met, a case should be allowed to proceed on behalf of the class proposed by the party. Rules Civ.Proc., Rule 23(a,b).

[12] Parties ⚿35.1
287k35.1 Most Cited Cases

Any question as to whether a case should proceed as a class in a doubtful case should be resolved in favor of allowing class certification. Rules Civ.Proc., Rule 23.

[13] Parties ⚿35.11
287k35.11 Most Cited Cases

Under "numerosity" provision of rule governing class actions, requiring that a class be so numerous that joinder of all of its members is impracticable, it is not necessary to establish that joinder is impossible; the test for "impracticability" of joining all members does not mean "impossibility" but only difficulty or inconvenience of joining all members. Rules Civ.Proc., Rule 23(a)(1).

[14] Parties ⚿35.13
287k35.13 Most Cited Cases

Only one named class representative, a member of the proposed class, is required for filing a class action. Rules Civ.Proc., Rule 23.

[15] Parties ⚿35.11
287k35.11 Most Cited Cases

A party seeking class certification is not required to prove the identity of each class member or the specific number of members. Rules Civ.Proc., Rule 23(a)(1).

[16] Parties ⚿35.11
287k35.11 Most Cited Cases

Under rule governing class actions, a court may properly rely on reasonable estimates of the number of members in the proposed class. Rules Civ.Proc., Rule 23(a)(1).

[17] Parties ⚿35.5
287k35.5 Most Cited Cases

Circuit court may not deny class certification motion merely because some members of the class have not suffered an injury or loss, or because there are members who may not want to participate in the class action. Rules Civ.Proc., Rule 23.

[18] Parties ⚿35.5
287k35.5 Most Cited Cases

[18] Parties ⚿35.41
287k35.41 Most Cited Cases

To demonstrate the existence of a class under rule governing class actions, it is not required that each class member be identified, but only that the class can be objectively defined; it is not a proper objection to certification that the class as defined may include some members who do not have claims because certification is conditional and may be altered, expanded, subdivided, or vacated as the case progresses toward resolution on the merits. Rules Civ.Proc., Rule 23.

[19] Parties ⚿35.69
287k35.69 Most Cited Cases

Class of approximately 5,000 individuals was sufficiently numerous to satisfy numerosity requirement of rule governing class actions, thus

supporting certification of class in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market. Rules Civ.Proc., Rule 23(a)(1).

[20] Parties 35.5
287k35.5 Most Cited Cases

Plaintiffs are not required, at the class certification stage, to identify the specific injuries of each class member. Rules Civ.Proc., Rule 23.

[21] Parties 35.17
287k35.17 Most Cited Cases

Under "commonality" requirement of rule governing class actions, requiring that the party seeking class certification show that there are questions of law or fact common to the class, a common nucleus of operative fact or law is usually sufficient; the threshold of commonality is not high, and requires only that resolution of the common questions affect all or a substantial number of the class members. Rules Civ.Proc., Rule 23(a)(2).

[22] Parties 35.17
287k35.17 Most Cited Cases

Commonality requirement of rule governing class actions requires that class members share a single common issue; however, not every issue in the case must be common to all class members. Rules Civ.Proc., Rule 23(a)(2).

[23] Parties 35.17
287k35.17 Most Cited Cases

Under commonality requirement for certification of a class, the common questions need be neither important nor controlling, and one significant common question of law or fact will satisfy this requirement. Rules Civ.Proc., Rule 23(a)(2).

[24] Parties 35.69
287k35.69 Most Cited Cases

Commonality requirement of rule governing class actions was met, thus supporting certification of class in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market; issues such as whether drug was not reasonably safe for its intended use, or whether manufacturers acted to mislead public about efficacy and safety of drug, were common to all or a substantial number of potential class members. Rules Civ.Proc., Rule 23(a)(1).

[25] Parties 35.13
287k35.13 Most Cited Cases

Under "typicality" requirement of rule governing class actions, requiring that claims or defenses of the representative parties be typical of the claims or defenses of the class, a representative party's claim or defense is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory; typicality only requires that class representatives' claims be typical of the other class members' claims, not that the claims be identical. Rules Civ.Proc., Rule 23(a)(3).

[26] Parties 35.13
287k35.13 Most Cited Cases

Although a class representative party's claim or defense must be typical of the claims or defenses of the class, when the claim arises out of the same legal or remedial theory, the presence of factual variations is normally not sufficient to preclude class action treatment. Rules Civ.Proc., Rule 23(a)(3).

[27] Parties 35.13
287k35.13 Most Cited Cases

The "typicality" requirement of rule governing class actions limits the claims of all class members to those fairly encompassed by the named plaintiff's claims. Rules Civ.Proc., Rule 23(a)(3).

[28] Parties 35.13
287k35.13 Most Cited Cases

To satisfy typicality requirement of rule governing class actions, mere anticipation that all class members will benefit from the suit is not enough, but interests sufficiently parallel to ensure a vigorous and full presentation of all potential claims for relief should satisfy requirement. Rules Civ.Proc., Rule 23(a)(3).

[29] Parties ⚿35.13
287k35.13 Most Cited Cases

Differences in the situation of each plaintiff or each class member do not necessarily defeat typicality requirement of rule governing class actions; the harm suffered by the named plaintiffs may differ in degree from that suffered by other members of the class so long as the harm suffered is of the same type. Rules Civ.Proc., Rule 23(a)(3).

[30] Parties ⚿35.13
287k35.13 Most Cited Cases

Although a class representative party's claim or defense must be typical of the claims or defenses of the class, the fact that a defense may be asserted against the named representatives, as well as some other class members, but not the class as a whole, does not destroy the representatives' status. Rules Civ.Proc., Rule 23(a)(3).

[31] Parties ⚿35.69
287k35.69 Most Cited Cases

Typicality requirement of rule governing class actions was met, thus supporting certification of class in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market; class was seeking relief related to medical monitoring due to use of drug, class members exposure to drug was claimed as basis for monitoring, and class alleged that manufacturers' wrongful conduct was directed toward State as a whole, not toward individual citizens. Rules Civ.Proc., Rule 23(a)(1).

[32] Parties ⚿35.13
287k35.13 Most Cited Cases

"Adequacy of representation" requirement of rule governing class actions, requiring that the party seeking class action status show that the representative parties will fairly and adequately protect the interests of the class, first tests the qualifications of attorneys to represent the class, and second, serves to uncover conflicts of interest between named parties and the class they seek to represent. Rules Civ.Proc., Rule 23(a)(4).

[33] Parties ⚿35.69
287k35.69 Most Cited Cases

Adequacy of representation requirement of rule governing class actions was met, thus supporting certification of class in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market; although damages sustained by class representatives and class members were not identical, class representatives shared strong interest in establishing liability of manufacturers, and sought same types of relief and damages as requested for other class members. Rules Civ.Proc., Rule 23(a)(4).

[34] Parties ⚿35.5
287k35.5 Most Cited Cases

Action or inaction by party opposing the class is directed to a class within the meaning of rule governing class actions, thus supporting certification of the class, even if it has taken effect or is threatened only as to one or a few members of the class, provided it is based on grounds that have general application to the class. Rules Civ.Proc., Rule 23(b)(2).

[35] Injunction ⚿4
212k4 Most Cited Cases

[35] Injunction ⚿5
212k5 Most Cited Cases

Injunctive relief embraces all forms of equitable judicial orders, whether they be mandatory or prohibitory.

[36] Parties ⚿35.5
287k35.5 Most Cited Cases

A request for a temporary restraining order or a preliminary injunction does not support certification of a class under rule governing class actions; class must be seeking a "final" injunction. Rules Civ.Proc., Rule 23(b)(2).

[37] Damages ⚿43
115k43 Most Cited Cases

Under rule governing class actions, after liability has been established, a court may exercise its equitable powers to establish and administer a

court- supervised medical monitoring program to oversee and direct medical surveillance, and provide for medical examinations and testing of members of a class. Rules Civ.Proc., Rule 23(b)(2).

[38] Parties ⚿35.71
287k35.71 Most Cited Cases

Rule governing class actions, providing that a class action may be appropriate when the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole, allows a court to exercise its equitable powers to award equitable relief under the Consumer Credit and Protection Act. West's Ann.W.Va.Code, 46-6-106; Rules Civ.Proc., Rule 23(b)(2).

[39] Parties ⚿35.69
287k35.69 Most Cited Cases

Manufacturers of drug acted, or refused to act, in a manner generally applicable to entire proposed class of prescription drug users, thus supporting certification of class in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market; drug was made by manufacturers, and manufacturers' conduct was directed toward discrete population of West Virginia diabetics who needed medication for control of their condition. Rules Civ.Proc., Rule 23(b)(2).

[40] Parties ⚿35.17
287k35.17 Most Cited Cases

That class members may eventually have to make an individual showing of damages does not preclude class certification. Rules Civ.Proc., Rule 23.

[41] Parties ⚿35.69
287k35.69 Most Cited Cases

Requirements for class action certification, that common questions predominate over individual questions and that class action be superior to other litigation methods, was satisfied, thus supporting certification of class in prescription drug users' action against drug manufacturers, alleging that manufacturers knowingly put defective product on the market; users' claims to recover medical monitoring costs for exposure to hazardous substance and for damages under the Consumer Protection Act contained class-wide issues, users intended to prove risks of disease as to all class members, and not on an individualized basis, and class action would permit litigation of claims where individual damages might be relatively small. Rules Civ.Proc., Rule 23(b)(3).

[42] Damages ⚿43
115k43 Most Cited Cases

For a plaintiff to recover medical monitoring costs for exposure to proven hazardous substance, the plaintiff must only show that the plaintiff has a significantly increased risk of contracting a particular disease relative to what would be the case in the absence of exposure; once that has been proven, the plaintiff must then show that medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease even if the disease it is intended to diagnose is not reasonably certain to occur.

[43] Consumer Credit ⚿18
92Bk18 Most Cited Cases

[43] Consumer Protection ⚿38
92Hk38 Most Cited Cases

[43] Consumer Protection ⚿40
92Hk40 Most Cited Cases

For a consumer to make out a prima facie case to recover damages for "any ascertainable loss" under Consumer Credit and Protection Act, the consumer is not required to allege a specific amount of actual damages; if the consumer proves that he or she has purchased an item that is different from or inferior to that for which he bargained, the "ascertainable loss" requirement is satisfied. West's Ann.W.Va.Code, 46A-6-106.

Syllabus by the Court

***1** 1. This Court will review a circuit court's order granting or denying a motion for class certification pursuant to Rule 23 of the *West Virginia Rules of Civil Procedure* [1998] under an abuse of discretion standard.

2. "An interpretation of the *West Virginia Rules of Civil Procedure* presents a question of law subject to a *de novo* review." Syllabus Point 4, *Keesecker v. Bird,* 200 W.Va. 667, 490 S.E.2d 754 (1997).

3. "A federal case interpreting a federal counterpart to a West Virginia rule of procedure may be persuasive, but it is not binding or controlling." Syllabus Point 3, *Brooks v. Isinghood,* --- W.Va. ----, 584 S.E.2d 531 (2003).

4. "The party who seeks to establish the propriety of a class action has the burden of proving that the prerequisites of Rule 23 of the West Virginia Rules of Civil Procedure have been satisfied." Syllabus Point 6, *Jefferson County Board of Education v. Jefferson County Education Association,* 183 W.Va. 15, 393 S.E.2d 653 (1990).

5. "Whether the requisites for a class action exist rests within the sound discretion of the trial court." Syllabus Point 5, *Mitchem v. Melton,* 167 W.Va. 21, 277 S.E.2d 895 (1981).

6. Nothing in either the language or history of Rule 23 of the *West Virginia Rules of Civil Procedure* [1998] gives a court any authority to conduct a preliminary inquiry into the merits of a suit in order to determine whether it may be maintained as a class action.

7. When a circuit court is evaluating a motion for class certification under Rule 23 of the *West Virginia Rules of Civil Procedure* [1998], the dispositive question is not whether the plaintiff has stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 have been met.

8. Before certifying a class under Rule 23 of the *West Virginia Rules of Civil Procedure* [1998], a circuit court must determine that the party seeking class certification has satisfied all four prerequisites contained in Rule 23(a)--numerosity, commonality, typicality, and adequacy of representation--and has satisfied one of the three subdivisions of Rule 23(b) . As long as these prerequisites to class certification are met, a case should be allowed to proceed on behalf of the class proposed by the party.

9. The numerosity provision of Rule 23(a)(1) of the *West Virginia Rules of Civil Procedure* [1998] requires that a class be so numerous that joinder of all of its members is "impracticable." It is not necessary to establish that joinder is impossible; rather, the test is impracticability. The test for impracticability of joining all members does not mean "impossibility" but only difficulty or inconvenience of joining all members.

10. "To demonstrate the existence of a class pursuant to Rule 23 of the West Virginia Rules of Civil Procedure, it is not required that each class member be identified, but only that the class can be objectively defined. It is not a proper objection to certification that the class as defined may include some members who do not have claims because certification is conditional and may be altered, expanded, subdivided, or vacated as the case progresses toward resolution on the merits." Syllabus Point 2, *State ex rel. Metropolitan Life Ins. Co. v. Starcher,* 196 W.Va. 519, 474 S.E.2d 186 (1996).

***2** 11. The "commonality" requirement of Rule 23(a)(2) of the *West Virginia Rules of Civil Procedure* [1998] requires that the party seeking class certification show that "there are questions of law or fact common to the class." A common nucleus of operative fact or law is usually enough to satisfy the commonality requirement. The threshold of "commonality" is not high, and requires only that the resolution of common questions affect all or a substantial number of the class members.

12. The "typicality" requirement of Rule 23(a)(3) of the *West Virginia Rules of Civil Procedure* [1998] requires that the "claims or defenses of the representative parties [be] typical of the claims or defenses of the class." A representative party's claim or defense is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory. Rule 23(a)(3) only requires that the class representatives' claims be typical of the other class members' claims, not that the claims be identical. When the claim arises out of the same legal or remedial theory, the presence of factual variations is normally not sufficient to preclude class action treatment.

13. The "adequacy of representation" requirement of Rule 23(a)(4) of the *West Virginia Rules of Civil Procedure* [1998] requires that the party seeking

class action status show that the "representative parties will fairly and adequately represent the interests of the class." First, the adequacy of representation inquiry tests the qualifications of the attorneys to represent the class. Second, it serves to uncover conflicts of interest between the named parties and the class they seek to represent.

14. Under Rule 23(b)(2) of the *West Virginia Rules of Civil Procedure* [1998], after liability has been established, a court may exercise its equitable powers to establish and administer a court-supervised medical monitoring program to oversee and direct medical surveillance, and provide for medical examinations and testing of members of a class.

15. Rule 23(b)(2) of the *West Virginia Rules of Civil Procedure* [1998] allows a court to exercise its equitable powers to award equitable relief under *W.Va.Code,* 46-6-106 [1974] of the West Virginia Consumer Credit and Protection Act.

16. For a consumer to make out a *prima facie* case to recover damages for "any ascertainable loss" under *W.Va.Code,* 46A-6-106 [1974], the consumer is not required to allege a specific amount of actual damages. If the consumer proves that he or she has purchased an item that is different from or inferior to that for which he bargained, the "ascertainable loss" requirement is satisfied.

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STARCHER, Chief Justice.

In this appeal from the Circuit Court of Raleigh County, we are asked to examine a circuit court order denying a motion to certify a class action for users of an allegedly defective prescription drug. After consideration of the briefs, the arguments of the parties, and all other matters of record, we conclude that the circuit court erred, and reverse and remand the case for proceedings as a class action.

I.
Facts & Background

***3** This case is a consolidation of several lawsuits filed by numerous plaintiffs who used Rezulin, an oral drug that was approved by the U.S. Food and Drug Administration ("FDA") in January 1997 to treat Type II (adult onset) diabetes. Rezulin is a trade name for the drug troglitazone. The defendants in the underlying action, and appellees and respondents before this Court, are Warner-Lambert Company and Parke-Davis & Company (a division of Warner- Lambert). From February 1997 until March 2000, the defendants marketed and sold Rezulin.

The plaintiffs allege that the defendants submitted

Rezulin to the FDA for evaluation in 1993, and touted the drug as a significant improvement on existing diabetes medications, while being just as safe to use. However, after reviewing data submitted by the defendants, an FDA investigator concluded in September 1996 that "the company has provided no proof that this drug ... constitutes a major therapeutic advance." The researcher also indicated that the data on Rezulin raised "some worrisome questions" because, compared to patients taking a placebo, significant numbers of patients taking Rezulin appeared to sustain liver damage. [FN1]

The plaintiffs allege that employees of the defendants met with the researcher's superiors at the FDA, resulting in the researcher's removal from the FDA's Rezulin evaluation. The researcher's reservations about the drug were never presented to the full committee investigating Rezulin, and the drug was approved for sale on January 29, 1997.

The plaintiffs contend that the defendants marketed Rezulin aggressively, and sought to convince both patients and doctors of the efficacy and safety of the drug. One of the advertisements produced by the defendants described Rezulin as a drug with breakthrough effectiveness and as having "Side Effects Comparable to Placebo." The defendants apparently made this claim despite the fact that their own clinical trial data showed Rezulin users were three to six times more likely to suffer liver injury than patients taking the placebo. The FDA later accused the company of making "false and misleading" statements.

The plaintiffs suggest that after a year of selling Rezulin, gross sales had exceeded $1 billion, and over 900,000 patients were taking the drug. At the same time, it appears that some patients were having severe liver problems as a result of taking Rezulin--and several had died. The plaintiffs contend that the defendants knew of these problems, but did little to advise doctors, patients, or the general public. [FN2] Further, to encourage doctors to prescribe the drug, the defendants appear to have offered doctors an indemnity plan that gave any doctor--who agreed to follow the Rezulin label--"experienced legal counsel," "reimbursement of litigation expenses," and "indemnification from liability" for prescribing the drug.

The defendants assert that as problems were discovered, the label on Rezulin changed, so that doctors could avoid or discover adverse liver reactions in patients. Despite changes in the labeling of Rezulin, and an increase in the frequency of liver-function testing of patients, the mortality of Rezulin users climbed. [FN3] Accordingly, on March 21, 2000, the defendants withdrew the drug from the marketplace.

***4** The plaintiffs filed several lawsuits in circuit courts in several West Virginia counties, and those separate lawsuits were transferred to the Circuit Court of Raleigh County and consolidated into the instant action. [FN4] The plaintiffs generally asserted that the defendants knowingly put a defective chemical--a drug--on the market, which they knew or should have known was defective at the time. The plaintiffs contended that the defendants' product caused the plaintiffs to be subject to an increased risk of liver disease and injury.

The plaintiffs' actions against the defendants sought, *inter alia,* to recover the costs of medical monitoring necessary to determine whether the plaintiffs have sustained, or will develop in the future, any injuries from using Rezulin. West Virginia law allows a cause of action for the recovery of medical monitoring costs, "where it can be proven that such expenses are necessary and reasonably certain to be incurred as a proximate result of a defendant's tortious conduct." Syllabus Point 2, *Bower v. Westinghouse Electric Corp.,* 206 W.Va. 133, 522 S.E.2d 424 (1999).

The tortious conduct alleged by the plaintiffs included, *inter alia,* that the defendants sold a product that was defective because it was unreasonably dangerous for its intended use. The plaintiffs assert that Rezulin was defective in both its design and manufacture, and defective because of insufficient labels and warnings. We set forth the standard for a defective product in Syllabus Point 4 of *Morningstar v. Black and Decker Mfg. Co.,* 162 W.Va. 857, 253 S.E.2d 666 (1979), where we stated:

> In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The standard of reasonable safeness is determined not by the

particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.

Another tort alleged by the plaintiffs is that the defendants, in their advertising and marketing of Rezulin, withheld material facts from patients and the public about problems with Rezulin, and thereby engaged in deceptive practices in violation of the West Virginia Consumer Credit and Protection Act, *W.Va.Code,* 46-6-101, *et seq.* ("Consumer Protection Act"). In addition to medical monitoring costs, the plaintiffs sought damages under the Consumer Protection Act and sought punitive damages.

The plaintiffs subsequently filed a motion seeking class certification under Rule 23 of the *West Virginia Rules of Civil Procedure* [1998]. The plaintiffs' definition of the proposed class was: "All persons who either consumed the drug Rezulin in West Virginia or consumed the drug Rezulin after having had the drugs prescribed or sold to them in West Virginia." The plaintiffs estimate that there are approximately 5,000 people who meet this class definition.

***5** The circuit court held a two-day hearing on the plaintiffs' class certification motion, and on December 12, 2001, issued an order denying the motion. [FN5] In reaching this conclusion, the circuit court made legal findings that, in effect, found that the plaintiffs could not prevail on the merits of their case. [FN6] The circuit court even went so far as to conclude that "the evidence shows that Rezulin was not a defective product" for the plaintiffs. Finally, the circuit court found that the plaintiffs failed to meet any of the requirements for the formation of a class action, as required by Rule 23 of the *Rules of Civil Procedure.* The plaintiffs subsequently filed a petition with this Court to appeal the circuit court's ruling denying certification.

After the circuit court denied their motion for class certification, the plaintiffs filed a motion asking the circuit court to remand their individual cases back to the original circuit courts from whence they were transferred, arguing that the circuit court's findings established that the plaintiffs' claims did not contain "common questions of law or fact" and were not properly consolidated before the circuit court under the terms of Rule 26.01 of the *Trial Court Rules* [1999]. Rule 26.01(c)(b) allows for cases to be consolidated in one circuit court if there are "two (2) or more civil actions pending in one or more circuit courts ... involving common questions of law or fact in 'personal injury mass torts' allegedly incurred upon numerous claimants in connection with widely available or mass marketed products[.]" Because the circuit court found that the questions of law and fact presented by each plaintiff's case were unique, and that the cases were better resolved on an individual basis, the plaintiffs argued that the circuit court was required to transfer their cases back to their original courts.

The circuit court refused to transfer the plaintiffs' cases. The plaintiffs then filed a petition for a writ of prohibition with this Court, seeking a writ to compel the circuit court to return their individual cases back to the counties where their complaints were originally filed.

We granted the plaintiffs' petition for appeal, and issued a rule to show cause why the plaintiffs' petition for a writ of prohibition should not be granted. Both issues were consolidated for consideration by the Court.

II.
Standard of Review

Our research indicates that courts review a lower court's decision granting or denying a motion for class certification with some deference, and generally look to whether the lower court abused its discretion. *See, e.g., Compass Bank v. Snow,* 823 So.2d 667, 671 (Ala.2001) (appellate court will apply "an abuse-of-discretion standard of review to a trial court's class-certification order, but we will review de novo the question whether the trial court applied the correct legal standard in reaching its decision."); *Associated Medical Networks, Ltd. v. Lewis,* 785 N.E.2d 230, 234 (Ind.App.2003) ("We review a trial court's decision to certify a class action for an abuse of discretion. An abuse of discretion occurs when the trial court's decision is clearly against the logic and effect of the facts and circumstances before the court."); *Chequet Systems, Inc. v. Montgomery,* 322 Ark. 742, 748, 911 S.W.2d 956, 958 (Ark.1995) ("This court reviews class certification under an abuse of discretion standard."); *Andrews v. American Tel. & Tel. Co.,* 95 F.3d 1014, 1022 (11th Cir.1996) ("We review the district court's grant of class certification for an

abuse of discretion.").

*6 The court in *Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 408 (5th Cir.1998) stated:

> [T]he district court maintains substantial discretion in determining whether to certify a class action, a decision we review only for abuse. Implicit in this deferential standard is a recognition of the essentially factual basis of the certification inquiry and of the district court's inherent power to manage and control pending litigation. Whether the district court applied the correct legal standard in reaching its decision on class certification, however, is a legal question that we review *de novo*.

(Citations omitted.)

[1] We therefore conclude that this Court will review a circuit court's order granting or denying a motion for class certification under an abuse of discretion standard. Of course, the circuit court's discretion must be exercised in the context of the appropriate rules of procedure.

[2] In the instant case, the circuit court was called upon to apply and interpret Rule 23 of the *West Virginia Rules of Civil Procedure*. As we stated in Syllabus Point 4 of *Keesecker v. Bird,* 200 W.Va. 667, 490 S.E.2d 754 (1997), "An interpretation of the *West Virginia Rules of Civil Procedure* presents a question of law subject to a *de novo* review."

[3] All of the parties in the instant case cite to numerous federal cases, in support of their various arguments. The circuit court, in its order denying class certification, appears to have relied almost exclusively on federal cases interpreting Rule 23 of the *Federal Rules of Civil Procedure*--and denying class certification--in drug or medical device actions. As we made clear in Syllabus Point 3 of *Brooks v. Isinghood,* --- W.Va. ----, 584 S.E.2d 531 (2003), "[a] federal case interpreting a federal counterpart to a West Virginia rule of procedure may be persuasive, but it is not binding or controlling." Our reasoning for this rule is to avoid having our legal analysis of our *Rules* "amount to nothing more than Pavlovian responses to federal decisional law." --- W.Va. at ----, 584 S.E.2d at 531, (*quoting Stone v. St. Joseph's Hosp. of Parkersburg,* 208 W.Va. 91, 112, 538 S.E.2d 389, 410 (2000) (McGraw, J., concurring, in part, and dissenting, in part) (holding that West Virginia disability discrimination law "is not mechanically tied to federal disability discrimination jurisprudence.")).

The plaintiffs are also seeking a writ of prohibition. A writ of prohibition lies "as a matter of right in all cases of usurpation and abuse of power, when the inferior court has not jurisdiction of the subject matter in controversy, or, having such jurisdiction, exceeds its legitimate powers." *W. Va.Code,* 53-1-1 [1923]. The law governing prohibition in this instance is set forth in Syllabus Point 4 of *State ex rel. Hoover v. Berger,* 199 W.Va. 12, 483 S.E.2d 12 (1996):

> In determining whether to entertain and issue the writ of prohibition for cases not involving an absence of jurisdiction but only where it is claimed that the lower tribunal exceeded its legitimate powers, this Court will examine five factors: (1) whether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief; (2) whether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal; (3) whether the lower tribunal's order is clearly erroneous as a matter of law; (4) whether the lower tribunal's order is an often repeated error or manifests persistent disregard for either procedural or substantive law; and (5) whether the lower tribunal's order raises new and important problems or issues of law of first impression. These factors are general guidelines that serve as a useful starting point for determining whether a discretionary writ of prohibition should issue. Although all five factors need not be satisfied, it is clear that the third factor, the existence of clear error as a matter of law, should be given substantial weight.

*7 With these standards in mind, we consider the parties' arguments.

III.
Discussion
A.
Purpose of Rule 23

Rule 23 of the *West Virginia Rules of Civil Procedure* governs the establishment of class actions in West Virginia. "In general, class actions are a flexible vehicle for correcting wrongs committed by large-scale enterprise upon individual

consumers." *McFoy v. Amerigas, Inc.,* 170 W.Va. 526, 533, 295 S.E.2d 16, 24 (1982). The rule is a procedural device that was adopted with the goals of economies of time, effort and expense, uniformity of decisions, the promotion of efficiency and fairness in handling large numbers of similar claims. *See, e.g., Life of the Land v. Land Use Commission of State of Hawaii,* 63 Haw. 166, 178, 623 P.2d 431, 442 (1981); *Lilian v. Commonwealth,* 467 Pa. 15, 19, 354 A.2d 250, 253 (1976).

Rule 23 provides trial courts with a tool to vindicate the rights of numerous claimants in one action when individual actions might be impracticable. *Hicks v. Milwaukee County,* 71 Wis.2d 401, 238 N.W.2d 509 (1976). A primary function of the class action is to provide a mechanism to litigate small damage claims which could not otherwise be economically litigated. As we stated in *State ex rel. Dunlap v. Berger,* 211 W.Va. 549, 562, 567 S.E.2d 265, 278 (2002) (*quoting Amchem Products, Inc. v. Windsor,* 521 U.S. 591, 617, 117 S.Ct. 2231, 2246, 138 L.Ed.2d 689, 709 (1997)):

> The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor.

[4][5][6] "The party who seeks to establish the propriety of a class action has the burden of proving that the prerequisites of Rule 23 of the West Virginia Rules of Civil Procedure have been satisfied." Syllabus Point 6, *Jefferson County Board of Education v. Jefferson County Education Association,* 183 W.Va. 15, 393 S.E.2d 653 (1990). As we have observed, "[w]hether the requisites for a class action exist rests within the sound discretion of the trial court." Syllabus Point 5, *Mitchem v. Melton,* 167 W.Va. 21, 277 S.E.2d 895 (1981). A circuit court should determine whether the prerequisites of a class action have been established "[a]s soon as practicable after the commencement of [the] action." Rule 23(c)(1).

B.
Consideration of the Merits of a Party's Claims

[7] A circuit court's consideration of a motion for class certification should not become a mini-trial on the merits of the parties' contentions. As we stated in *Burks v. Wymer,* 172 W.Va. 478, 486 307 S.E.2d 647, 654 (1983)(*quoting Eisen v. Carlisle and Jacquelin,* 417 U.S. 156, 177, 94 S.Ct. 2140, 2152, 40 L.Ed.2d 732, 748 (1974)), "[N]othing in either the language or history of Rule 23 ... gives a court any authority to conduct a preliminary inquiry into the merits of a suit in order to determine whether it may be maintained as a class action."

***8** [8] Allowing inquiry into the substantive merits of a party's claims or defenses in the context of a class certification motion deprives the party of the right to trial by jury on the claims. *See Guarantee Ins. Agency Co. v. Mid-Contintental Realty Corp.,* 57 F.R.D. 555, 564 (N.D.Ill., 1972). Because Rule 23 requires a circuit court to rule on a class certification motion "as soon as practicable," consideration of the merits of the parties' claims would often amount to a court considering summary judgment before the parties have had adequate time for discovery. Moreover, consideration of the merits of a party's claims or defenses is discouraged by the express language of the rule, because Rule 23(c)(1) states that courts should rule upon, alter, or amend any decision about a class certification motion "before the decision on the merits." [FN7]

[9] Accordingly, when a circuit court is evaluating a motion for class certification under Rule 23, the dispositive question "is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met." *Miller v. Mackey Intern., Inc.,* 452 F.2d 424, 427 (5th Cir.1971).

[10] The circuit court's order in the instant case indicates that the circuit judge did both consider and make determinations regarding the merits of the parties' claims and defenses while considering the motion for class certification. For example, the circuit court concluded that class-wide relief was not possible because "at least 95% of the people who took Rezulin 'tolerated the drug well without developing any form of liver reaction [.]" ' The circuit court concluded that the representative plaintiffs were not typical of class members because they appeared to have adverse liver problems-- but then also concluded that "the evidence shows that Rezulin was not a defective product for [the

plaintiffs]." These factual conclusions were not relevant to the circuit court's consideration of whether the requirements of Rule 23 were met, and as it appears the circuit court substantially turned its decision to deny the plaintiffs' class certification motion on the merits of the plaintiffs' and defendants' evidence, the circuit court thereby abused its discretion.

C.
Requirements for Class Certification under Rule 23(a)

[11] Rule 23 specifies that the party seeking class certification must meet all four requirements under Rule 23(a), and meet one of the three requirements under Rule 23(b). [FN8] The four prerequisites that a party must meet under Rule 23(a) before a case may be certified as a class action are: (1) that the class is so numerous that joinder of all members is impractical (the "numerosity" requirement); (2) that there are questions of law or fact common to the class (the "commonality" requirement); (3) that the claims or defenses of the representative parties are typical of those of the class (the "typicality" requirement); and (4) that the representative parties will adequately protect the interests of the class (the "adequacy of representation" requirement).

***9** Rule 23(b) sets forth the following types of class actions that are maintainable and their requirements, of which the moving party must qualify under only one:

> An action may be maintained as a class action if the prerequisites of subdivision (a) are satisfied, and in addition:
> (1) The prosecution of separate actions by or against individual members of the class would create a risk of
> (A) Inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the party opposing the class, or
> (B) Adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; or
> (2) The party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole; or
> (3) The court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.

[12] In sum, before certifying a class, a circuit court must determine that the party seeking class certification has satisfied all four prerequisites contained in Rule 23(a)--numerosity, commonality, typicality, and adequacy of representation--and has satisfied one of the three subdivisions of Rule 23(b). [FN9] *See Lukenas v. Bryce's Mountain Resort, Inc.,* 538 F.2d 594, 595 n. 2 (4th Cir.1976) ("To maintain a class action, one must satisfy all four of the provisions of [Rule 23] section (a) and one of the subdivisions of section (b).") As long as these prerequisites to class certification are met, a case should be allowed to proceed on behalf of the class proposed by the party. *Mitchem v. Melton,* 167 W.Va. 21, 28, 277 S.E.2d 895, 899 (1981) ("If the requirements of Rule 23 are met, then the class should be allowed."). Any question as to whether a case should proceed as a class in a doubtful case should be resolved in favor of allowing class certification. *Esplin v. Hirschi,* 402 F.2d 94, 101 (10th Cir.1968), *cert denied,* 394 U.S. 928, 89 S.Ct. 1194, 22 L.Ed.2d 459 (1969) ("[T]he interests of justice require that in a doubtful case ... any error, if there is to be one, should be committed in favor of allowing the class action.").

***10** As we set forth below in further detail, the circuit court concluded that the plaintiffs in the instant case failed to meet any of the requirements under either Rule 23(a) or (b).

1. *The "Numerosity" Requirement of Rule 23(a)(1)*

[13] The numerosity provision of Rule 23(a)(1)

requires that a class be so numerous that joinder of all of its members is "impracticable." It is not necessary to establish that joinder is impossible; rather, the test is impracticability. "[T]he test for 'impracticability' of joining all members does not mean 'impossibility' but only difficulty or inconvenience of joining all members." *Mitchem v. Melton,* 167 W.Va. 21, 33, 277 S.E.2d 895, 902 (1981) (citations omitted). *See also In re Oxford Health Plans, Inc.,* 191 F.R.D. 369, 374 (S.D.N.Y.2000) ("Impracticability means difficulty or inconvenience of joinder; the rule does not require impossibility of joinder."); *Goldstein v. North Jersey Trust Co.,* 39 F.R.D. 363, 367 (S.D.N.Y.1966) ("the meaning to be ascribed to the word 'impracticable,' ... should be 'impractical,' 'unwise' or 'imprudent' rather than 'incapable of being performed' or 'infeasible[.]' ")

[14] There is no "magic minimum number that breathes life into a class ... and lack of knowledge of the exact number of persons affected is not a bar to certification[.]" *Clarkson v. Coughlin,* 783 F.Supp. 789, 798 (S.D.N.Y.1992). Only one named class representative--who is a member of the proposed class--is required for filing a class action. *Fiore v. Hudson County Employees Pension Comm'n,* 151 N.J.Super. 524, 526-29, 377 A.2d 702, 703-04 (App.Div.1977). Courts have certified class actions when there have been as few as seventeen to twenty members of the class (*Arkansas Educ. Ass'n v. Board of Educ.,* 446 F.2d 763 (8th Cir.1971)); thirty-five to seventy members (*Fidelis Corp. v. Litton Industries, Inc.,* 293 F.Supp. 164 (S.D.N.Y.1968)); seventy members (*Korn v. Franchard Corp.,* 456 F.2d 1206 (2d Cir.1972)); 123 members (*Temple University v. Pennsylvania Dept. of Public Welfare,* 30 Pa.Cmwlth. 595, 374 A.2d 991 (1977)); and 204 members (*Ablin v. Bell Telephone Co.,* 291 Pa.Super. 40, 435 A.2d 208 (1981)).

[15][16] A party seeking class certification is not required to prove the identity of each class member or the specific number of members. *Stambaugh v. Kansas Dept. of Corrections,* 151 F.R.D. 664, 673 (D.Kan.1993). A court may properly rely on reasonable estimates of the number of members in the proposed class. *Rex v. Owens ex rel. Oklahoma,* 585 F.2d 432, 436 (10th Cir.1978).

[17][18] Furthermore, a circuit court may not deny a class certification motion merely because some members of the class have not suffered an injury or loss, or because there are members who may not want to participate in the class action. As we stated in Syllabus Point 2 of *State ex rel. Metropolitan Life Ins. Co. v. Starcher,* 196 W.Va. 519, 474 S.E.2d 186 (1996):

> ***11** To demonstrate the existence of a class pursuant to Rule 23 of the West Virginia Rules of Civil Procedure, it is not required that each class member be identified, but only that the class can be objectively defined. It is not a proper objection to certification that the class as defined may include some members who do not have claims because certification is conditional and may be altered, expanded, subdivided, or vacated as the case progresses toward resolution on the merits.

In support of our holding in the *Metropolitan Life* case, we relied upon *Joseph v. General Motors Corp.,* 109 F.R.D. 635, 639 (D.Colo.1986), where the district court concluded that "the fact that the class may initially include persons who have not had difficulties with their V8-6-4 engines or who do not wish to have these purported problems remedied is not important at this stage of the litigation."

[19] In the instant case, the plaintiffs allege that there are approximately 5,000 individuals who meet their proposed class definition, of which only about 2,000 are represented by plaintiffs' counsel. [FN10] The circuit court, however, concluded that "the plaintiffs have not shown that West Virginians who sustained an injury from Rezulin use are 'so numerous that joinder of all members is impracticable,' as required by Rule 23(a)(1)." We find that it would be highly impractical for plaintiffs' counsel to find, let alone join in the instant action, all persons who either consumed the drug Rezulin in West Virginia or consumed the drug Rezulin after having had the drugs prescribed or sold to them in West Virginia. We therefore find that the circuit court erred in concluding that the plaintiffs failed to meet the numerosity requirement of Rule 23(a).

[20] We also note that the circuit court's ruling regarding numerosity hinged on consideration of the merits of the parties' claims and defenses. The circuit court held that the numerosity requirement was not met because the plaintiffs failed to "identif[y] anyone else in the State who allegedly has a Rezulin-related injury." We reiterate that the

plaintiffs were not required to show, at the class certification stage, that any person who has a claim also currently has a Rezulin-related physical injury. The plaintiffs are primarily seeking relief relating to medical monitoring. The plaintiffs are not required, at the class certification stage, to identify the specific injuries of each class member, and it was error for the circuit court to so hold.

2. The "Commonality" Requirement of Rule 23(a)(2)

[21] The "commonality" requirement of Rule 23(a)(2) requires that the party seeking class certification show that "there are questions of law or fact common to the class." "A common nucleus of operative fact [or law] is usually enough to satisfy the commonality requirement." *Rosario v. Livaditis,* 963 F.2d 1013, 1017-18 (7th Cir.1992). "The threshold of 'commonality' is not high," and "requires only that resolution of the common questions affect all or a substantial number of the class members." *Jenkins v. Raymark Industries, Inc.,* 782 F.2d 468, 472 (5th Cir.1986).

***12** [22][23] Commonality requires that class members share a single common issue. *Baby Neal for and by Kanter v. Casey,* 43 F.3d 48, 56 (3d Cir.1994). "However, not every issue in the case must be common to all class members." *O'Connor v. Boeing North American, Inc.,* 184 F.R.D. 311, 330 (C.D.Cal.1998). The common questions need be neither important nor controlling, and one significant common question of law or fact will satisfy this requirement. *Georgia State Conference of Branches of NAACP v. Georgia,* 99 F.R.D. 16, 25 (S.D.Ga.1983). In other words, "[t]he class 'as a whole' must raise at least one common question of law or fact to make adjudication of the issues as a class action appropriate to conserve judicial and private resources." Philip Stephen Fuoco and Robert F. Williams, "Class Actions in New Jersey State Courts," 24 Rutgers L.J. 737, 752 (1993).

The leading commentator on class action law summarizes the rule in this way:

> The Rule 23(a)(2) prerequisite requires only a single issue common to the class. Individual issues will often be present in a class action, especially in connection with individual defenses against class plaintiffs, rights of individual class members to recover in the event a violation is established, and the type or amount of relief individual class members may be entitled to receive. Nevertheless, it is settled that the common issues need not be dispositive of the litigation. The fact that class members must individually demonstrate their right to recover, or that they may suffer varying degrees of injury, will not bar a class action; nor is a class action precluded by the presence of individual defenses against class plaintiffs.

A. Conte and H. Newberg, 1 *Newberg on Class Actions, 4th Ed.,* § 3:12 at 314- 315 (2002).

[24] In the instant case, the circuit court denied class certification under Rule 23(a)(2) because "the evidence shows that Rezulin was not a defective product" for the plaintiffs, and that therefore "the defendants have shown that the common issues identified by the plaintiffs are not in fact common."

The plaintiffs, however, have identified numerous issues which they contend are common to all potential class members, including whether the drug was not reasonably safe for its intended use by the public as a whole; whether the drug was defective because its instructions and warnings were not adequate for the reasonable, prudent consumer; whether the defendants acted with each other and third parties to mislead physicians and the public about the efficacy and safety of the drug; and whether the defendants violated the Consumer Protection Act in its actions toward West Virginia consumers. We find that issues such as these are common to all or a substantial number of potential class members, and therefore conclude that the circuit court erred in finding otherwise.

3. The "Typicality" Requirement of Rule 23(a)(3)

"The first two prerequisites of Rule 23, joinder impracticability and common questions, focus on characteristics of the class.... The second two prerequisites, typicality and adequate representation, focus instead on the desired characteristics of the class representative." 1 *Newberg on Class Actions, 4th Ed.,* § 3:13 at 316-17.

***13** [25][26] The "typicality" requirement of Rule 23(a)(3) requires that the "claims or defenses of the representative parties [be] typical of the claims or defenses of the class." A representative party's claim or defense "is typical if it arises from the

same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory." 1 *Newberg on Class Actions, 4th Ed.,* § 3:13 at 328. *In accord, In re American Medical Systems, Inc.,* 75 F.3d 1069, 1082 (6th Cir.1996). Rule 23(a)(3) only requires that the class representatives' claims be typical of the other class members' claims, not that the claims be identical. *Christman v. American Cyanamid Co.,* 92 F.R.D. 441, 451 (N.D.W.Va.1981). When the claim arises out of the same legal or remedial theory, the presence of factual variations is normally not sufficient to preclude class action treatment. *United Broth. of Carpenters and Joiners of America, Local 899 v. Phoenix Associates, Inc.,* 152 F.R.D. 518, 522 (S.D.W.V.1994).

[27][28] This "typicality" requirement limits the claims of all class members "to those fairly encompassed by the named plaintiff's claims." *General Tel. Co. v. E.E.O.C.,* 446 U.S. 318, 330, 100 S.Ct. 1698, 1706, 64 L.Ed.2d 319, 330 (1980). The rationale behind the requirement is that a class representative with typical claims "will pursue his or her own self-interest in the litigation, and in so doing, will advance the interests of the class members[.]" 1 *Newberg on Class Actions, 4th Ed.,* § 3:13 at 325. "[M]ere anticipation that all class members will benefit from the suit ... is not enough. But interests sufficiently parallel to ensure a vigorous and full presentation of all potential claims for relief should satisfy Rule 23(a)(3)." *Weiss v. York Hosp.,* 745 F.2d 786, 810 (3d Cir.1984), *cert. denied,* 470 U.S. 1060, 105 S.Ct. 1777, 84 L.Ed.2d 836 (1985).

[29][30] However, "differences in the situation of each plaintiff or each class member do not necessarily defeat typicality: The harm suffered by the named plaintiffs may differ in degree from that suffered by other members of the class so long as the harm suffered *is of the same type.*" *Boggs v. Divested Atomic Corp.,* 141 F.R.D. 58, 65 (S.D.Ohio 1991) (citations omitted). Furthermore, "[t]he fact that a defense may be asserted against the named representatives, as well as some other class members, but not the class as a whole, does not destroy the representatives' status." *Shutts v. Phillips Petroleum Co.,* 235 Kan. 195, 208, 679 P.2d 1159, 1172 (1984), *aff'd in part and rev'd in part on other grounds,* 472 U.S. 797, 105 S.Ct. 2965, 86 L.Ed.2d 628 (1985).

[31] In the instant case, the circuit court ruled that "representative plaintiffs must exist for each type of ... assurance, or medical advice each plaintiff received," and then concluded that "[b]ecause Rezulin was effective for each proposed class representative, without the side-effects that they experienced from other diabetes medications, these individuals are not typical of any putative class members[.]" The Court also found that the claims made by the plaintiffs "are so varied that there can be no 'typical' Rezulin user."

***14** After reviewing the record and briefs of the parties, we conclude that the plaintiffs are asserting that the class is seeking relief related to medical monitoring due to their use of Rezulin. Thus, because their exposure to Rezulin alone is claimed as the basis for this monitoring, the class and the representatives have nearly identical claims. Additionally, the plaintiffs are alleging that the defendants violated the Consumer Protection Act through conduct directed toward West Virginia as a whole, not toward individual citizens. We therefore perceive that the claims asserted by the class representatives are typical of those of other class members, and find that the circuit court erred in holding otherwise.

4. *The "Adequacy of Representation" Requirement under Rule 23(a)(4)*

[32] The "adequacy of representation" requirement of Rule 23(a)(4) requires that the party seeking class action status show that the "representative parties will fairly and adequately protect the interests of the class." "First, the adequacy of representation inquiry tests the qualifications of the counsel to represent the class. Second, it serves to uncover conflicts of interest between named parties and the class they seek to represent." *In re Prudential Ins. Co. of America Sales Practices Litigation,* 148 F.3d 283, 312 (3d Cir.1998) (internal citations omitted). *In accord, Black v. Rhone- Poulenc, Inc.,* 173 F.R.D. 156, 162 (S.D.W.V.1996) ("When assessing the class representatives' ability to adequately represent the interest of the class, the Court must consider the abilities of both the attorneys who represent the class representatives, and the class representatives themselves.")

The first factor in determining the vigor of representation concerns the representatives' attorneys' resources to investigate class claims and to contact other class members. *See Bowen v. General Motors Corp. A.C. Spark Plug Div.,* 542 F.Supp. 94, 100-02 (N.D.Ohio 1981); *Ingram v. Joe Conrad Chevrolet, Inc.,* 90 F.R.D. 129, 132 (E.D.Ky.1981). It also concerns the competence and experience of class counsel. *Susman v. Lincoln American Corp.,* 561 F.2d 86, 90 (7th Cir.1977); *Harris v. General Development Corp.,* 127 F.R.D. 655, 662 (N.D.Ill.1989). The defendants in the instant case do not challenge the ability of the plaintiffs' counsel to vigorously and competently represent the purported class.

[33] In the instant case, the defendants challenge the second factor and argue that the interests of the class representatives are antagonistic to the interests of the class members, because the plaintiffs assert that the class representatives have sustained certain specific injuries from using Rezulin, while the proposed class includes both injured and uninjured persons. The circuit court agreed with the defendants, and ruled that "the named plaintiffs cannot adequately represent putative class members who are asymptomatic." The circuit court also found that "all former West Virginia Rezulin users may not desire class certification ... because those with strong cases may well be better off going it alone." (Citations omitted.)

***15** After reviewing the record and briefs of the parties, we find that the class representatives share a strong interest in establishing the liability of the defendants, and seek the same types of relief and damages as requested for other class members. While the defendants correctly indicate that the damages sustained by some of the current class representatives and class members may not be identical, other courts have not found this to be an impediment to class certification. *See, e.g., Black v. Rhone-Poulenc, Inc.,* 173 F.R.D. 156 (S.D.W.Va.1996) (class action members and representatives suffered different physical injuries, some only "inconvenience and emotional distress," from exposure to chemicals from chemical plant fire); *Watson v. Shell Oil Co.,* 979 F.2d 1014 (5th Cir.1992) (class members and representatives sustained different personal injury and property damage claims from oil refinery explosion); *Coburn v. 4-R Corp.,* 77 F.R.D. 43 (E.D.Ky.1977) (class members and representatives sustained different damages as result of Beverly Hills Supper Club fire).

Moreover, the alternative to class adjudication--trying all 5,000 claims together as a "mass" proceeding consolidated for trial under Rule 42 of the *Rules of Civil Procedure*--suffers from the same problems. The courts of this State have successfully managed to overcome and try, *en masse,* cases that have included vast differences in injuries between multiple plaintiffs, and cases where the plaintiffs were seeking punitive damages. *See, e.g., State ex rel. Mobil Corp. v. Gaughan,* 211 W.Va. 106, 563 S.E.2d 419 (2002)("presumably several thousands of asbestos personal injury claims"); *State ex rel. Allman v. MacQueen,* 209 W.Va. 726, 551 S.E.2d 369 (2001) ("approximately 8,000 asbestos plaintiffs"); *Abbott v. Owens-Corning Fiberglas Corp.,* 191 W.Va. 198, 444 S.E.2d 285 (1994) (1,015 plaintiffs exposed to asbestos). The class action vehicle appears to be a superior option to consolidation, as it gives the circuit court greater control over class representatives and class counsel. The circuit court therefore erred on this point.

D.
Requirements for Class Certification under Rule 23(b)

In its order denying class certification, the circuit court concluded that the plaintiffs had failed to meet any of the three requirements under Rule 23(b). On appeal, the plaintiffs assert that class certification is appropriate under Rules 23(b)(2) and (3); the plaintiffs do not assert a position as to whether they meet the qualifications of Rule 23(b)(1), and we therefore do not discuss this part of the rule.

1. *Equitable Relief under Rule 23(b)(2)*

The plaintiffs argue that because the same defendants acted in the same manner toward the entire class, the trial court may exercise its equitable powers through Rule 23(b)(2) in fashioning relief to establish a medical monitoring fund for the class members. This equitable fund would not pay damages directly to any members of the class, but would rather provide a court-administered fund that could pay to medical providers the cost of any testing.

***16** The defendants argue, and the circuit court below agreed, that in order for the plaintiffs to be successful in their claim for medical monitoring damages, they must first prove that Rezulin was defective, or prove that the Consumer Protection Act was violated. The defendants assert that whether a product was defective, or whether the Consumer Protection Act was violated, involves individual factual determinations that are different for each member of the proposed class. The defendants therefore argue that a class action is not feasible under Rule 23(b)(2) because the proposed class will not be "cohesive."

Rule 23(b)(2) allows a court to certify a class action if "the party opposing the class has acted or refused to act on grounds generally applicable to the class," and the representatives are seeking "final injunctive relief or corresponding declaratory relief" for the entire class. Class action treatment is particularly useful in this situation because it will determine the propriety of the behavior of the party opposing the class in a single action. *Fuller v. Fruehauf Trailer Corp.,* 168 F.R.D. 588, 602 (E.D.Mich.1996).

[34] The term "generally applicable" in Rule 23(b)(2) signifies "that the party opposing the class does not have to act directly against each member of the class." *Quigley v. Braniff Airways, Inc.,* 85 F.R.D. 74, 79 (N.D.Tex.1979) (*quoting* Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, 7A *Fed. Practice & Procedure, Civ.2d,* § 1775). *See also,* 2 *Newberg on Class Actions, 4th Ed.,* § 4:11 at 55 ("the defendant's conduct described in the complaint need not be directed or damaging to every member of the class"). The key is whether the actions of the party opposing the class would affect all persons similarly situated, so that the acts apply generally to the whole class. *Santiago v. City of Philadelphia,* 72 F.R.D. 619 (E.D.Pa.1976). Courts have also interpreted the "generally applicable" requirement to mean that the party opposing the class either has acted in a consistent manner toward members of the class so that his actions may be viewed as part of a pattern of activity, *see, e.g., Mortimore v. F.D.I.C.,* 197 F.R.D. 432 (W.D.Wash.2000) (defendant improperly calculated adjustable rate mortgages), or has established or acted pursuant to a regulatory scheme common to all class members. *See, e.g., Geen v. Foschio,* 94 F.R.D. 177 (W.D.N.Y.1982)(government policy automatically denied licenses to anyone with certain medical conditions). Action or inaction is directed to a class within the meaning of Rule 23(b)(2) even if it has taken effect or is threatened only as to one or a few members of the class, provided it is based on grounds that have general application to the class. *Gibbs v. Titelman,* 369 F.Supp. 38, 52 (E.D.Pa.1973), *reversed on other grounds,* 502 F.2d 1107 (3d Cir.1974).

[35][36] The second prerequisite to bringing an action under Rule 23(b)(2) is that final injunctive or declaratory relief must be requested against the party opposing the class. Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, 7A *Federal Practice & Procedure, Civ.2d,* § 1775 at 457. Injunctive relief embraces all forms of equitable judicial orders, whether they be mandatory or prohibitory. *Id.* at 457-58. But the class must be seeking a "final" injunction; a request for a temporary restraining order or a preliminary injunction does not qualify under Rule 23(b)(2). *Id.* at 458- 61.

***17** Other jurisdictions have concluded that a court's equitable powers, as specified under Rule 23(b)(2), are appropriate for establishing and administering a medical monitoring program. For instance, in *Friends for All Children, Inc. v. Lockheed Aircraft Corp.,* 746 F.2d 816, 828-31 (D.C.Cir.1984), the court upheld a district court's preliminary injunction compelling the defendants to pay money to the court to create a medical monitoring fund. In *Day v. NLO,* 851 F.Supp. 869, 886 (S.D.Ohio 1994), the court approved the creation of a court-supervised fund under Rule 23(b)(2), holding that "[t]he use of the Courts injunctive powers to oversee and direct medical surveillance is vastly superior to a lump sum monetary payment... A court supervised fund will also assure that the medical monitoring damages will be used to compensate for medical examinations and tests actually administered." *See also Barth v. Firestone Tire and Rubber Co.,* 661 F.Supp. 193, 203-205 (N.D.Cal.1987) (affirming plaintiffs' right to seek a medical monitoring injunction because the exposure creating the need for surveillance was "the very essence of irreparable harm"); *Gibbs v. E.I. DuPont De Nemours & Co., Inc.,* 876 F.Supp. 475, 481 (W.D.N.Y.1995) ("A court-administered fund which goes beyond payment of the costs of monitoring an individual

plaintiff's health to establish pooled resources for the early detection and advances in treatment of the disease is injunctive in nature rather than 'predominantly money damages' and therefore is properly certified under Rule 23(b)(2)"); *Hansen v. Mountain Fuel Supply,* 858 P.2d 970, 982 (Utah 1993) (use of a court-supervised fund to administer medical monitoring "is a highly appropriate use of the Court's equitable powers"); *Potter v. Firestone Tire & Rubber Co.,* 6 Cal.4th 965, 25 Cal.Rptr.2d 550, 863 P.2d 795, 825 (1993) (holding that court-supervised funds for medical monitoring for mass-exposure toxic torts cases best serve public health interests).

[37] We find that under Rule 23(b)(2), after liability has been established, a court may exercise its equitable powers to establish and administer a court-supervised medical monitoring program to oversee and direct medical surveillance, and provide for medical examinations and testing of members of a class.

[38] Furthermore, the Consumer Protection Act, specifically *W.Va.Code,* 46A-6-106(1) [1974], states that when a plaintiff has proven an ascertainable loss caused by some unfair trade practice by the defendant, "[t]he court may, in its discretion, provide such equitable relief as it deems necessary and proper." We therefore also find that Rule 23(b)(2) of the *West Virginia Rules of Civil Procedure* allows a court to exercise its equitable powers to award equitable relief under *W.Va.Code,* 46A-6-106 of the Consumer Protection Act.

[39] The plaintiffs assert that all members of the proposed class took the same drug, and were subject to the same risk of possible injuries. The drug was made by the same defendants, and the defendants' conduct was directed toward a discrete population: the plaintiffs, all West Virginia diabetics who needed medication for control of their condition. After examining the record and briefs of the parties, we conclude that the plaintiffs have met the initial requirements of Rule 23(b)(2) and shown that the defendants acted, or refused to act, in a manner generally applicable to the entire proposed class. The circuit court therefore erred in holding otherwise.

2. *"Predominance" and "Superiority" Requirements under Rule 23(b)(3)*

***18** Under Rule 23(b)(3), a class action may be certified to proceed on behalf of a class if the trial court finds "that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members," and finds that a class action "is superior to other available methods for the fair and efficient adjudication of the controversy."

The predominance criterion in Rule 23(b)(3) is a corollary to the "commonality" requirement found in Rule 23(a)(2). While the "commonality" requirement simply requires a showing of common questions, the "predominance" requirement requires a showing that the common questions of law or fact outweigh individual questions.

"A conclusion on the issue of predominance requires an evaluation of the legal issues and the proof needed to establish them. As a matter of efficient judicial administration, the goal is to save time and money for the parties and the public and to promote consistent decisions for people with similar claims." *In the Matter of Cadillac V8-6-4 Class Action,* 93 N.J. 412, 430, 461 A.2d 736, 745 (1983) . The predominance requirement is not a rigid test, but rather contemplates a review of many factors, the central question being whether "adjudication of the common issues in the particular suit has important and desirable advantages of judicial economy compared to all other issues, or when viewed by themselves." 2 *Newberg on Class Actions, 4th Ed.,* § 4:25 at 174.

In discussing which test courts should use to determine whether common questions predominate, one court observed:

> The requirement that common questions of law and fact predominate over individual issues is the greatest barrier to (b)(3) certification. In determining the existence of predomination, courts have applied various standards. Some mechanically weigh the substantive issues requiring individual proof against issues that can be resolved entirely on a class basis. Others mechanically balance the estimated time necessary to litigate common issues against the time predicted for individual issues, in order to determine predomination. The Federal Rules Advisory Committee and those courts sympathetic to class actions have adopted still another approach. The Advisory Committee

> suggests that the goal of predominance is to determine whether judicial economies can be fairly achieved after examining all the circumstances of the case.

Black v. Rhone-Poulenc, Inc., 173 F.R.D. at 163-164 (*quoting* James W. Elrod, Comment, *The Use of Federal Class Actions in Mass Toxic Pollution Torts,* 56 Tenn.L.Rev. 243, 267-68 (1988)).

[40] The predominance requirement does not demand that common issues be dispositive, or even determinative; it is not a comparison of the amount of court time needed to adjudicate common issues versus individual issues; nor is it a scale-balancing test of the number of issues suitable for either common or individual treatment. 2 *Newberg on Class Actions, 4th Ed.,* § 4:25 at 169-173. Rather, "[a] single common issue may be the overriding one in the litigation, despite the fact that the suit also entails numerous remaining individual questions." *Id.* at 172. The presence of individual issues may pose management problems for the circuit court, but courts have a variety of procedural options under Rule 23(c) and (d) to reduce the burden of resolving individual damage issues, including bifurcated trials, use of subclasses or masters, pilot or test cases with selected class members, or even class decertification after liability is determined. As the leading treatise in this area states, "[c]hallenges based on ... causation, or reliance have usually been rejected and will not bar predominance satisfaction because those issues go to the right of a class member to recover, in contrast to underlying common issues of the defendant's liability." 2 *Newberg on Class Actions, 4th Ed.,* § 4.26 at 241. "That class members may eventually have to make an individual showing of damages does not preclude class certification." *Smith v. Behr Process Corp.,* 113 Wash.App. 306, 323, 54 P.3d 665, 675 (2002) (citations omitted).

***19** [41] The defendants assert that the plaintiffs will be required at trial to show individual causation and injury caused by some product defect, before being eligible for medical monitoring relief. Furthermore, the defendants contend that each individual plaintiff will be required to show, under the Consumer Protection Act, that the defendants committed an unfair trade practice or other violation of the Act that caused the plaintiff to buy Rezulin. The defendants therefore argue that, because there are substantial individual issues inherent in the plaintiffs' claims, these individual issues predominate over issues common to the class.

The plaintiffs, however, take the position that there are no essentially individual issues in their class-related claims. They therefore take the position that their claims, for medical monitoring under *Bower v. Westinghouse Elec. Corp.,* 206 W.Va. 133, 522 S.E.2d 424 (1999) and for damages under the Consumer Protection Act, contain exclusively class-wide issues that predominate under Rule 23(b)(3).

To begin, as we stated in Syllabus Point 2 of *Bower,* "[a] cause of action exists under West Virginia law for the recovery of medical monitoring costs, where it can be proven that such expenses are necessary and reasonably certain to be incurred as a proximate result of a defendant's tortious conduct." In *Bower,* we rejected the contention that a claim for medical monitoring costs must rest upon the existence of present and proven physical harm. To the contrary, "[t]he 'injury' that underlies a claim for medical monitoring--just as with any other cause of action sounding in tort--is 'the invasion of any legally protected interest." 206 W.Va. at 139, 522 S.E.2d at 430.

[42] For a plaintiff to obtain relief under *Bower,* the plaintiff must only show "that the plaintiff has a significantly increased risk of contracting a particular disease relative to what would be the case in the absence of exposure." 206 W.Va. at 142, 522 S.E.2d at 433. Once that has been proven, the plaintiff must then show that "medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease ... even if the disease it is intended to diagnose is not reasonably certain to occur." 206 W.Va. at 140, 522 S.E.2d at 431 (citations omitted).

We stated a six-part test in Syllabus Point 3 of *Bower:*

> In order to sustain a claim for medical monitoring expenses under West Virginia law, the plaintiff must prove that (1) he or she has, relative to the general population, been significantly exposed; (2) to a proven hazardous substance; (3) through the tortious conduct of the defendant; (4) as a proximate result of the exposure, plaintiff has suffered an increased risk of contracting a serious

latent disease; (5) the increased risk of disease makes it reasonably necessary for the plaintiff to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of the exposure; and (6) monitoring procedures exist that make the early detection of a disease possible.

***20** The plaintiffs assert that the entire class, as a whole, meets this six-part test. First and second, the plaintiffs contend all Rezulin users were "significantly exposed" to a hazardous substance relative to the general population. The defendants argue that a drug approved by the FDA can never be a "hazardous substance;" we reject this argument outright, because a defective drug, particularly one whose FDA approval was allegedly achieved as a result of incomplete, misleading or negligently-conducted research by the manufacturer, can be a substance that is exceptionally hazardous to the public. We agree with the plaintiffs that both of these factors are common to the entire class.

Third, the exposure must be the result of tortious misconduct of the defendants. We perceive from the record that much of the evidence in the instant case will be directed toward showing that the defendants' previously discussed tortious conduct was directed toward the public as a whole, and not toward any individual plaintiff.

The final three elements of the *Bowers* criteria are less clear from the record, but it appears that the plaintiffs' evidence will show that they have an increased risk of contracting a serious disease, and that the increased risk makes it reasonably necessary for the plaintiffs to undergo periodic medical examinations using existing monitoring procedures, different from what would have been required of the plaintiffs in the absence of their use of Rezulin. It also appears from the record that the plaintiffs intend to prove these final elements as to all class members, and not on an individualized basis.

The plaintiffs contend that the injuries or diseases that result from the use of Rezulin are not related to the dose taken by each patient. Instead, they contend that taking the drug triggered, in some instances, an idiosyncratic reaction that resulted in known and testable injuries. Accordingly, because all plaintiffs in the proposed class took Rezulin, the plaintiffs assert that all members of the class are at risk for an idiosyncratic reaction and injury. We conclude that the circuit court erred in holding that common issues regarding medical monitoring did not predominate over individual issues.

We must also resolve the question of whether common issues predominate over individual issues regarding the plaintiffs' action under the Consumer Protection Act. *W.Va.Code,* 46A-6-106(1) authorizes a cause of action for "[a]ny person who purchases or leases goods or services and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice prohibited or declared to be unlawful by the provisions of this article[.]" [FN11] *W.Va.Code,* 46A-6-102(f)(13) [1996] prohibits the "act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, *whether or not any person has in fact been misled, deceived or damaged thereby.*" (Emphasis added.)

***21** As stated previously, the circuit court interpreted these two statutes as requiring that each putative class member would have to prove that a violation of the Consumer Protection Act caused him or her to purchase Rezulin, and to prove specific damages resulting from that purchase.

We have never examined *W.Va.Code,* 46A-6-106 in detail. In *Orlando v. Finance One of W.Va., Inc.,* 179 W.Va. 447, 369 S.E.2d 882 (1988), we gave the statute a cursory glance in approving a circuit court's dismissal of a consumer's attempt to recover damages from a lender for an unconscionable clause in a loan contract--even though the lender never tried to enforce the clause. We quoted the text of *W.Va.Code,* 46A-6-106, and concluded that because the lender "made no attempt to enforce Clause # 14, the appellants have suffered no 'ascertainable loss of money or property' as a result of the inclusion of Clause # 14 in the loan contract.... Thus, while the inclusion of Clause # 14 was an unfair practice, we find that the appellants are not entitled to recover damages." 179 W.Va. at 453, 369 S.E.2d at 888.

Other jurisdictions interpreting statutes similar to ours have concluded that consumers can meet the "ascertainable loss" requirement without proving that the consumer suffered a specific monetary loss based upon the unfair or deceptive acts or practices. In the leading case of *Hinchliffe v. American Motors Corp.,* 184 Conn. 607, 440 A.2d 810 (1981) , the court interpreted a Connecticut statute that allowed a cause of action by "[a]ny person who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment of a method, act or practice prohibited by section 42- 110b ...." 184 Conn. at 612, 440 A.2d at 813. The Connecticut court concluded that the words "any ascertainable loss" do not require a plaintiff to prove a specific amount of actual damages in order to make out a *prima facie* case. 184 Conn. at 612-613, 440 A.2d 810, 813-814.

> Our conclusion finds initial support in the language chosen by the legislature when it framed § 42-110g(a). Where drafters meant "actual damages," they employed those exact words. The use of different terms within the same sentence of a statute plainly implies that differing meanings were intended. Moreover, the inclusion of the word "ascertainable" to modify the word "loss" indicates that plaintiffs are not required to prove actual damages of a specific dollar amount. "Ascertainable" means "capable of being discovered, observed or established."
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> "Loss" has been held synonymous with deprivation, detriment and injury. It is a generic and relative term. "Damage," on the other hand, is only a species of loss. The term "loss" necessarily encompasses a broader meaning than the term "damage."
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> Whenever a consumer has received something other than what he bargained for, he has suffered a loss of money or property. That loss is ascertainable if it is measurable even though the precise amount of the loss is not known. CUTPA is not designed to afford a remedy for trifles. In one sense the buyer has lost the purchase price of the item because he parted with his money reasonably expecting to receive a particular item or service. When the product fails to measure up, the consumer has been injured; he has suffered a loss. In another sense he has lost the benefits of the product which he was led to believe he had purchased. That the loss does not consist of a diminution in value is immaterial, although obviously such diminution would satisfy the statute.

***22** 184 Conn. at 613, 440 A.2d at 814 (citations omitted). *See also, Scott v. Western Intern. Surplus Sales, Inc.,* 267 Or. 512, 515, 517 P.2d 661, 662-63 (1973) ("Under the statute there is no need to allege or prove the amount of the 'ascertainable loss'; the plaintiff is only claiming the minimum of $200 which is recoverable if an ascertainable loss of any amount is proved .... 'Ascertainable' can reasonably be interpreted to mean, capable of being discovered, observed or established. As we have already stated, the amount of the loss is immaterial if only $200 is sought."); *Miller v. American Family Publishers,* 284 N.J.Super. 67, 87-89, 663 A.2d 643, 655 (1995) ("To satisfy the 'ascertainable loss' requirement, a plaintiff need prove only that he has purchased an item partially as a result of an unfair or deceptive practice or act and that the item is different from that for which he bargained.").

[43] We conclude that for a consumer to make out a *prima facie* case to recover damages for "any ascertainable loss" under *W.Va.Code,* 46A-6-106, the consumer is not required to allege a specific amount of actual damages. If the consumer proves that he or she has purchased an item that is different from or inferior to that for which he bargained, the "ascertainable loss" requirement is satisfied.

The plaintiffs assert that in a class action, a difference in claims over the amount of damages is not sufficient to defeat class certification in an action for a refund. *See In re: Auction Houses Antitrust Litig.,* 193 F.R.D. 162, 167 (S.D.N.Y.2000) (rejecting defendant's argument that common issues did not predominate because damages could not be calculated using the same method for every member of the class); *In re NASDAQ Market-Makers Antitrust Litigation,* 169 F.R.D. 493, 523 (S.D.N.Y.1996) ("neither a variety of prices nor negotiated prices is an impediment to class certification"); *Wolgin v. Magic Marker Corp.,* 82 F.R.D. 168, 176 (E.D.Pa.1979) ("[T]he 'overwhelming weight of authority' holds that the need for individual damages calculations does not diminish the appropriateness of class action certification where common questions as to liability predominate"). Based upon this authority, we conclude that the circuit court erred in holding that the individual damages allegedly suffered by the plaintiffs as a result of the defendants' alleged misconduct predominated over the common

questions relating to the defendants conduct.

Rule 23(b)(3) also requires a showing "that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." This requirement focuses upon a comparison of available alternatives. The defendants contend in the instant case, that case management problems will render a class adjudication impossible. We disagree. While the management of any complex class action is likely to present a challenge, there is a myriad of management devices available to the circuit court under Rule 23. But forcing numerous plaintiffs to litigate the alleged misconduct of the defendants in hundreds or thousands of repeated individual trials, especially where a plaintiff's individual damages may be relatively small, runs counter to the very purpose of a class action:

> ***23** It must also be remembered that manageability is only one of the elements that goes into the balance to determine the superiority of a class action in a particular case. Other factors must also be considered, as must the purposes of Rule 23, including: conserving time, effort and expense; providing a forum for small claimants; and deterring illegal activities.

2 *Newberg on Class Actions, 4th Ed.*, § 4.32 at 277-78. As we perceive the existing record, a class action appears to be a superior method to any other method for expeditiously litigating the claims of the parties. The plaintiffs have therefore met the requirements of Rule 23(b)(3), and the circuit court erred in holding otherwise.

E.
Plaintiffs' Petition for a Writ of Prohibition

Finally, we must briefly address the plaintiffs' petition for a writ of prohibition. The plaintiffs seek a writ of prohibition to have their individual claims returned from the Circuit Court of Raleigh County to the circuit courts where they were originally filed. The plaintiffs' petition is based entirely on the circuit court's conclusion that individual issues predominated in their cases, and that there were no common issues for resolution.

As our opinion makes clear, we believe that the plaintiffs have established that "common questions of law or fact" exist. Accordingly, we need not address their contention that their cases do not meet the standard for "mass litigation" under Rule 26.01 of the *Trial Court Rules.*

The writ of prohibition will therefore be denied.

IV.
Conclusion

The circuit court erred in considering the merits of the parties' claims at this stage of the proceedings, and in denying the plaintiffs' motion for class certification. The circuit court's order of December 12, 2001, is therefore reversed, and the case is remanded for further proceedings.

Because of our resolution of the class action questions, the plaintiffs' petition for a writ of prohibition is denied.

Reversed and Remanded; Writ Denied.

Justice DAVIS, deeming herself disqualified, did not participate in the decision of this case.

FN1. As the researcher stated:

> With respect to the liver, LFT abnormalities were more frequent in the treated groups (0/ to 2, placebo v. troglitazone [Rezulin]). More ominously, 0/70 cases of jaundice were observed in placebo-treated patients, as opposed to the 9/140 seen in troglitazone [Rezulin]-treated patients.
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> ...
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> So, [their] statement that the safety profile of troglitazone [Rezulin] has been found to be no different than that of placebo-treated patients is to be taken with a grain of salt .... Thus, it is unwise to force the FDA to hastily introduce a drug into the marketplace with such potential for worrisome toxicity, by invoking a significant therapeutic effect that hasn't been proven to exist.

FN2. For example, Rezulin was approved for sale in Great Britain in late 1997, but after two months' experience, the drug was removed from the market. On December 2,

1997, the United Kingdom's Medicines Control Agency stated that "based on present information, the risks of troglitazone therapy outweigh the potential benefits. It has therefore been voluntarily withdrawn from the UK as from 1 December 1997[.]" The agency's basis for concern was that it had "now become aware of over 130 cases (6 fatal) worldwide of hepatic [liver] reactions to troglitazone."

FN3. As one court noted:
In February 2000, the company released a statement claiming that it believed that there were no liver-failure deaths attributable to Rezulin after the June 1999 label change. The day after this statement was made, the FDA discredited it, saying the agency had been informed of six cases of liver failure with onset after July 1999, of which at least three resulted in death.
In March 2000, doctors at the FDA and elsewhere became even more concerned about Rezulin, with one doctor writing to others that "at each juncture in the management of Rezulin's liver failure risk, hindsight shows that [the monitoring] had little or no effect and that Warner-Lambert's assertions that the liver failure problem was solved were proved false."
Desiano v. Warner-Lambert Co., 326 F.3d 339, 344 (2d Cir.2003).

FN4. The plaintiffs actually filed sixteen different lawsuits in several different counties throughout West Virginia. On November 17, 2000, then-Chief Justice Elliott Maynard stayed all proceedings in all pending Rezulin cases and referred them to the Mass Litigation Panel, pursuant to *West Virginia Trial Court Rule* 26.01. Based upon the Panel's recommendation, on December 14, 2000, the Chief Justice referred all pending Rezulin cases to the Circuit Court of Raleigh County for consolidated proceedings under Rule 26.01.

FN5. The circuit court's order has, for unknown reasons, somehow been published on Westlaw. *See* 2001 WL 1818442.

FN6. For example, the circuit court indicated that there is "[n]o medical evidence that any patient ever developed a latent [liver] injury attributable to any drug months or years after the patient discontinued the drug," and that if a patient stopped taking a drug that caused a liver injury, the patient's liver healed. The circuit court went on to also find that any liver function testing would have insufficient sensitivity to detect liver problems--but if problems were detected, there would be no way of knowing if the liver problem was caused by Rezulin or some other drug.
The circuit court also fashioned, as a matter of law, eight specific "criteria for medical monitoring" based upon the testimony of an expert retained by the defendants, and concluded that the plaintiffs had failed to meet these criteria. These criteria, which we discuss later in the text, are not present in our leading case on medical monitoring. *Bower v. Westinghouse Electric Corp.*, 206 W.Va. 133, 522 S.E.2d 424 (1999). For example, the circuit court concluded that *Bower* requires the "[e]xistence of a relatively low-cost monitoring test" that has a "low physical 'cost' to the patient," that is, a test that is not " 'too invasive' and risky." The circuit court went on to find--based upon the testimony of the defendants' experts--that a needle biopsy of the liver is the only "bedrock test" that could be used by the plaintiffs to monitor for liver problems. The circuit court concluded that the liver biopsy "fail[ed] the medical monitoring criterion that ANY medical monitoring tests be 'low cost' and not too invasive."

FN7. This is not to say, however, that Rule 23 mandates that a circuit court in every case must fully certify a class before

proceeding to a consideration of the merits. In *McFoy v. Amerigas, Inc.*, 170 W.Va. 526, 295 S.E.2d 16 (1982), we examined a situation where the circuit court granted summary judgment on liability against a defendant, and then certified a class action on behalf of a class of plaintiffs. We approved of this procedure, stating: Where the factual circumstances of a case make it appropriate to determine liability before determining the class of plaintiffs, it is within the court's discretion to do so. The applicable requirement under the Federal Rules is that determination of class standing be made "as soon as practicable after the commencement of the action," Rule 23(c)(1), *Fed.R.Civ.P.* (1966). The Third Circuit, Sixth Circuit and District of Columbia Circuit have all allowed the trial court to make its class action determination at the entry of final judgment, or after. *McLaughlin v. Wohlgemuth,* 535 F.2d 251 (3rd Cir., 1976) ; *Larionoff v. U.S.*, 175 U.S.App.D.C. 32, 533 F.2d 1167 (1976) *aff'd,* 431 U.S. 864, 97 S.Ct. 2150, 53 L.Ed.2d 48 (1977); *Alexander v. Aero Lodge No. 735, Int'l. Ass'n. of Machinists and Aerospace Workers, AFL-CIO,* 565 F.2d 1364 (6th Cir., 1977), *cert. denied,* 436 U.S. 946, 98 S.Ct. 2849, 56 L.Ed.2d 787 (1978). We find this flexibility reasonable so long as the defendant is aware that a determination of class action standing is a distinct possibility.... This decision is in harmony with the Third Circuit's tactic in *Katz v. Carte Blanche Corp.*, 496 F.2d 747 (1974) (*en banc*), *cert. denied,* 419 U.S. 885, 95 S.Ct. 152, 42 L.Ed.2d 125 (1974) that permitted plaintiffs to proceed in a test case and move, if successful, for later consideration of class certification, and also with the general federal practice that permits plaintiffs to "amend up" to a class complaint. 170 W.Va. at 531, 295 S.E.2d at 21-22.

FN8. In the Syllabus of *Burks v. Wymer,* 172 W.Va. 478, 307 S.E.2d 647 (1983), we established the following guidelines for circuit courts to follow in evaluating whether a class action could be certified under the 1960 version of Rule 23:

The following factors should be considered by a trial judge in deciding whether a "spurious" class action may be maintained under *W.Va.R.Civ.P.* 23(a)(3):

(1) whether common questions of law or fact predominate over any questions affecting only individual members;

(2) whether other means of adjudicating the claims and defenses are practicable or inefficient;

(3) whether a class action offers the most appropriate means of adjudicating the claims and defenses;

(4) whether members not representative parties have a substantial interest in individually controlling the prosecution or defense of separate actions;

(5) whether the class action involves a claim that is or has been the subject of a class action, a government action, or other proceeding;

(6) whether it is desirable to bring the class action in another forum;

(7) whether management of the class action poses unusual difficulties; (8) whether any conflict of laws issues involved pose unusual difficulties; and

(9) whether the claims of individual class members are insufficient in the amounts or interests involved, in view of the complexities of the issues and the expenses of the litigation, to afford significant relief to the members of the class.

The version of Rule 23 that was discussed by the Court in *Burks v. Wymer* was based upon the 1938 version of Rule 23 of the *Federal Rules of Civil Procedure;* the federal rule was last amended in 1998. The West Virginia version of Rule 23 was amended by this Court in 1998, bringing it more into alignment with the federal rule.

While the factors outlined in *Burks v. Wymer* remain helpful to courts evaluating the propriety of motions for class certification, we no longer believe they are sufficient under our current version of Rule 23.

FN9. A prior version of Rule 23 contained the following requirements:
The appropriateness of a class action under Rule 23(a) of the West Virginia Rules of Civil Procedure depends on a determination that the persons constituting the class are so numerous as to make it impracticable to bring them all before the court, that the named individuals joined will fairly insure the adequate representation of the class, and that the rights asserted against or on behalf of those making up the class are of the character specified in the rule.
Syllabus Point 5, *Jefferson County Bd. of Educ. v. Jefferson County Educ. Assoc.*, 183 W.Va. 15, 393 S.E.2d 653 (1990). The rule has since been amended, and Rule 23 now contains additional requirements.

FN10. It is unclear whether lawsuits have been filed on behalf of these individuals, or whether the plaintiffs' attorneys actually represent these individuals or simply know that these individuals wish to assert claims against the defendants.
The circuit court denied certification, in part, because it determined that the "statute of limitation would vary from person to person." We note that this is an overbroad statement of the law. Courts usually hold that the timely "commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action." *American Pipe & Construction Co. v. Utah,* 414 U.S. 538, 554, 94 S.Ct. 756, 766, 38 L.Ed.2d 713, 727 (1974). *See also, Vaccariello v. Smith & Nephew Richards, Inc.,* 94 Ohio St.3d 380, 763 N.E.2d 160 (2002) (class action filed in federal court; when class action status was later denied by federal court, state court held that statute of limitation had been tolled during pendency of class action, and allowed case to proceed in state court); Syllabus Point 2, *Waltrip v. Sidwell Corp.,* 234 Kan. 1059, 678 P.2d 128 (1984) ("The right of all putative members of a proposed class in an action filed pursuant to K.S.A. 60-223 to file a separate action is saved or preserved pending the determination of whether the initial case shall be maintained as a class action."); *Crown, Cork & Seal Company, Inc. v. Parker,* 462 U.S. 345, 354, 103 S.Ct. 2392, 2397, 76 L.Ed.2d 628, 636 (1983) ("Once the statute of limitations has been tolled, it remains tolled for all members of the putative class until class certification is denied. At that point, class members may choose to file their own suits or to intervene as plaintiffs in the pending action."); *Nolan v. Sea Airmotive, Inc.,* 627 P.2d 1035, 1042 (Alaska, 1981) ("the filing of a class action under Civil Rule 23 ordinarily tolls the statute of limitations as to all members of the class, whether or not named in the complaint.").

FN11. *W.Va.Code,* 46A-6-106(1) [1974] states:
Any person who purchases or leases goods or services and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice prohibited or declared to be unlawful by the provisions of this article, may bring an action in the circuit court of the county in which the seller or lessor resides or has his principal place of business or is doing business, or as provided for in sections one and two, article one, chapter fifty-six of this Code, to recover actual damages or two hundred dollars, whichever is greater. The court may, in its discretion, provide such equitable relief as it deems necessary or proper.

2003 WL 21518104, --- S.E.2d ----, 2003 WL 21518104 (W.Va.)

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